ROBUST SUMMARY
OF INFORMATION ON

Substance Group:

WAXES
And
RELATED MATERIALS

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NB. Reliability of data included in this summary has been assessed using the approach described by Klimisch, et al.

Klimisch, H. J., Andreae, M. and Tillman, U, (1997)
A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data.
Regulatory Toxicology and Pharmacology 25, 1-5.

1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type :
Substance type : Petroleum product
Physical status : Solid

Remark : This robust summary covers the waxes and related products which includes:
Slack wax
Petrolatum
Paraffin wax
Microcrystalline wax

Petroleum waxes are obtained from paraffinic refinery streams in lubricating oil manufacture.
The wax is separated by filtering a chilled solution of waxy oil in a selected solvent (usually a mixture of methyl ethyl ketone and toluene).

SLACK WAX is obtained from the dewaxing of refined or unrefined vacuum distillate fractions. If the material has been separated from residual oil fractions it is frequently called PETROLATUM.
The slack waxes are de-oiled by solvent crystallization or "sweating" processes to manufacture commercial waxes with low oil content. The oil that is separated from these processes is known as FOOTS OIL.
The refined petroleum waxes are known as PARAFFIN WAXES.
MICROCRYSTALLINE WAXES have higher molecular weights than the paraffin waxes and consist of substantial amounts of iso- and cycloalkanes.

1.2 SYNONYMS AND TRADENAMES

Remark : Paraffin wax
Slack wax
Petrolatum
Microcrystalline wax

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

Type of limit : TLV (US)
Limit value : 2 mg/m³

Remark : The UK HSE have established an occupational exposure limit of 2 mg/m³ (8 hour TWA) and a 15 minute Short Term Exposure Limit (STEL) of 6 mg/m³.

(2) (51)

1.13 REVIEWS

Memo : EU SCF

Remark : The EU Scientific Committee for Food (SCF) reviewed the available information on mineral hydrocarbons, which included the petroleum waxes. Their opinion was published in 1995. The SCF reached the following conclusion:

There are sufficient data to allow a full Group ADI of 0-20 mg/kg bw for waxes conforming to the following specification: -

Highly refined waxes derived from petroleum based or synthetic hydrocarbon feedstocks, with

viscosity	not less than 11 mm³/s (cSt) at 100 °C
Carbon number	not less than 25 at the 5% boiling point
Average molecular weight	not less than 500

(47)

Memo : WHO JECFA

Remark : The WHO Joint Expert Committee on Food Additives (JECFA) reviewed the available information on food grade mineral hydrocarbons. Their evaluation was published in 1996. With respect to waxes they made the following conclusions:

Substance	**ADI (mk/kg bw)**
Paraffin waxes	
LMPW (Low melting point wax)	ADI withdrawn
IMPW (Intermediate melting point wax)	ADI withdrawn
Microcrystalline waxes	
HSW (High sulfur wax)	0-20
HMPW (High Melting Point Wax)	0-20

(36)

Memo : CTFA

Remark : An independent expert panel reviewed data supplied to them by the Cosmetics, Toiletries & Fragrances Association (CTFA). A report of the evaluation was published in 1984. However, few experimental details are available and the conclusions of the panel cannot be verified. Their overall conclusion was:

Toxicological test data on Ozokerite, Ceresin, Montan Wax, Paraffin, Microcrystalline Wax, Emulsifying Wax N.F., and Synthetic Beeswax are presented. Based on the documented animal and clinical test data, it is concluded that these waxes are safe for use as cosmetic ingredients in the present practices of concentration and use.

(21)

2.1 MELTING POINT

Value : 36 - 60 °C
Method : ASTM D127
Year : 1999
GLP : No data
Test substance : Petrolatum

(7) (15) (23) (38)

Value : 43 - 63 °C
Method : ASTM D127
Year : 1999
GLP : No data
Test substance : Slack wax

(7) (15) (23) (38)

Value : 43 - 68 °C
Method : ASTM D127
Year : 1999
GLP : No data
Test substance : Paraffin wax

(7) (15) (23) (38)

Value : 60 - 95 °C
Method : ASTM D127
Year : 1999
GLP : No data
Test substance : Microcrystalline wax

(7) (15) (23) (38)

2.2 BOILING POINT

Value : ca. 350 - 500 °C

Remark : In a survey of the composition of food grade waxes and oils the boiling range for paraffin wax was reported to be 350-485°C. Microcrystalline waxes boiled in excess of 500 °C. While boiling points for slack wax and petrolatum are not available, because their constituent hydrocarbons are produced from vacuum distillation, they will have boiling points above 300°C.

(12) (14)

2.3.1 GRANULOMETRY

Remark : Not relevant

2.4 VAPOUR PRESSURE

Remark : All the materials in the category are solid or semi-solid at room temperature. Any vapor pressure attributable to these materials would be from the oil component of the material (if it is present). As discussed in the Lubricating Oil Basestocks test plan, the vapor pressures of lubricating base oils are expected to be negligible and have been determined in one study to be 1.7×10^{-4} Pa.

2.5 PARTITION COEFFICIENT

Log pow : 4.7 -≥ 6.
Method : Calculated: KOWWIN Version 1.65 (EPIWIN)
Year : 2001
Test substance : Wax and related materials

Remark : As hydrocarbon number increases above C13, as is the case for the majority of the wax constituents, Log P values >6 are predicted. Substances having Log P estimates greater than 6 are characterized by extremely large molecular weight and subsequent hydrophobicity, therefore no significant aqueous exposures or bioaccumulation are expected to occur.

Result : Octanol-water partition coefficients (log P or Kow) were modeled with isomers of the lowest molecular weight component (C13 hydrocarbons) in waxes. These partitioning estimates are characteristic of only a small fraction of component molecules in a given wax. Because of the diversity of compounds encompassing waxes, it is not feasible to model the physicochemical endpoints for each potential compound. Since molecular weight and structural conformation determines in large part the solubility and vapor pressure characteristics of the hydrocarbons, modeling focused on the lower molecular weight hydrocarbons. These would be selected C13 and C20 hydrocarbons since waxes consist mostly of C20 to C85 compounds, with some minimal percent of C13 through C20 hydrocarbons. Therefore, the majority of the physicochemical modeling was performed on various paraffinic, naphthenic and aromatic representatives containing 13 and C20 carbon atoms.
The Log pow ranges from 4.7 to ≥6.7

Reliability : (2) Valid with restrictions

(44)

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Value : 0.027 - 5.96 mg/l at 25 °C
Method : WSKOW Version 1.36 (EPIWIN)
Year : 2001
Test substance : Wax and related materials

Remark : The water solubility of waxes cannot be determined due to their complex mixture characteristics. Therefore, the water solubility of individual C13 hydrocarbons was modeled. The highest solubilities would be exhibited by only a small fraction of the hydrocarbon molecules present in waxes. Increasing carbon number results in rapidly decreasing solubility, so that the most-soluble (predominantly methyl-substituted diaromatic) C18 and C20 analogues yield model values of 0.01195 and 0.00125 mg/l, respectively. Higher molecular weight (higher carbon number) components are even less water soluble. Based on water solubility modeling for C13 components of complex mixtures, aqueous solubilities of these waxes are typically much less than 1 ppm, due to differential partitioning of components between the aqueous and organic phases.

Reliability : (2) Valid with restrictions

(16)

2.8 AUTO FLAMMABILITY

Remark : Not relevant

2.9 FLAMMABILITY

Result : Non flammable

2.10 EXPLOSIVE PROPERTIES

Result : Not relevant

2.11 OXIDIZING PROPERTIES

Result : Not relevant

2.14 ADDITIONAL REMARKS

Memo : The information given in this section represent the range of values that are found for the various waxes and related products.

Remark :

Physico chemical properties for typical grades of wax and petrolatum are shown in the following table (CONCAWE, 1999). See also Bennet (1975), Kauffman et al (1993) and EWF (1990).

Melting Point (°C)	Kinematic viscosity at 100 °C	Oil content (%m/m)	Carbon number range	Penetration (25°C) (mm²/sec)
ASTM D127	ASTM D445	ASTM D721 or D3235	ASTM D2505	ASTM D1321 or D937*
Slack wax				
45-85	3-30	2-30	12-85	9-80*
Lower Melt Paraffin Wax				
43-74	3-10	<2.5	18-75	9-50*
Microcrystalline Wax				
60-95	10-30	<5	23-85	3-60*
Petrolatum				
36-60	3-30	>10	12-85	>6

NB * The second value given for penetration was determined using method D937

(7) (15) (23) (38)

3.1.1 PHOTODEGRADATION

Type	:	Atmospheric oxidation
Method	:	Calculated: AOPWin Version 1.89 (EPIWIN)
Year	:	2001
Test substance	:	Wax and related materials
Remark	:	Although waxes typically have low vapor pressures, volatilization of some lower molecular weight components exhibit relatively high atmospheric oxidation half-lives. Therefore, those compounds that may partition to the atmosphere will be removed through indirect photochemical degradation. All modeled components exhibited rapid degradation in the atmosphere; the value presented represents both the most volatile component and the longest modeled half-life. All other modeled C13 components had both lower volatility and shorter half-lives.
Result	:	t½ = 0.913 days (10.96 hr) for most volatile C13 component modeled
Reliability	:	(2) Valid with restrictions

(43)

3.1.2 STABILITY IN WATER

Remark	:	Hydrolysis of an organic chemical is the transformation process in which a water molecule or hydroxide ion reacts to form a new carbon-oxygen bond. Chemicals that have a potential to hydrolyze include alkyl halides, amides, carbamates, carboxylic acid esters and lactones, epoxides, phosphate esters, and sulfonic acid esters. Materials in the waxes category are not subject to hydrolysis, as they lack these reactive groups.
Reliability	:	(1) Valid without restriction

(31)

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type	:	Calculated according to Mackay Level I
Media	:	Soil, air, water, suspended sediment, and sediment
Year	:	2000
Remark	:	Fugacity-based computer modeling indicated that the majority of high molecular weight hydrocarbons with carbon numbers of C20 and greater in waxes would be distributed to soil. Percent distribution estimates were modeled with C13 to C29 branched paraffins as this class of wax hydrocarbons shows the greater distribution to air. Aromatic compounds with carbon numbers from C13 through C85 will partition principally to soil. Linear paraffins and naphthenes distribute to both soil and air, with increasing partitioning to soil for hydrocarbons greater than C20 as vapor pressure decreases. Physical properties input are

those calculated by the EPIWIN Estimation 3.04 program and included in this summary. The default model assumptions were used when performing the fugacity estimates. Since the majority of hydrocarbon components in waxes are primarily normal paraffins of C20 and greater, with moderate to minimal amounts of naphthenics, isoparaffins and trace amounts of aromatics, volatility is not a significant fate process for these petroleum substances due to negligible vapor pressures at ambient temperatures and their high molecular weight. As hydrocarbon number increases above C20, partitioning to soil is the predominant behavior of these compounds.

Result : **Carbon No. Isoparaffin** **% Distribution**

	Air	Soil	Water	Sediment	Susp. Sediment	Biota
C13	98	1.9	$7E^{-3}$	$4E^{-2}$	$8E^{-3}$	$1E^{-4}$
C18	69	30	$4E^{-4}$	0.68	$2E^{-2}$	$2E^{-3}$
C20	33	65	$2E^{-5}$	1.4	$3E^{-2}$	$4E^{-3}$
C21	18	80	$5E^{-6}$	1.8	$5E^{-2}$	$4E^{-3}$
C22	12	86	$2E^{-6}$	1.9	$6E^{-2}$	$4E^{-3}$
C24	6	92	$2E^{-7}$	2.1	$6E^{-2}$	$5E^{-3}$
C26	1	97	$2E^{-8}$	2.1	$7E^{-2}$	$5E^{-3}$
C29	0.1	98	$9E^{-10}$	2.2	$7E^{-2}$	$6E^{-3}$

Reliability : (2) Valid with restrictions

(41)

3.5 BIODEGRADATION

Type : Aerobic
Inoculum : Oil-contaminated soil from land-farming project
Contact time : 84 day(s)
Result : 80% in 28 days; inherently and extensively biodegradable
Deg. product : No
Method : Modified OECD 301B (significant modification, actually shake flask test)
Year : 1989
GLP : Yes
Test substance : Paraffin wax CAS 8002-74-2

Remark : Paraffin wax residue analysis showed less than 10% parent hydrocarbons and some hydrocarbon enrichment from contaminated soil inoculum after 28 days.

Result : Degradation % after time 80% of $ThCO_2$ after 28 days; 87% after 84 days (paraffins)

66% of $ThCO_2$ after 28 days; 77% after 84 days (intermediate wax)

Kinetic (for sample, positive and negative controls)
Reference (sodium acetate) - Not Reported
Test substance - 80% (paraffin, 28 days),
66% (intermediate wax, 28days)

Breakdown Products No other than residual HCs

Test condition : Inoculum: Soil was collected from land-farm used by the investigators to treat oil-contaminated soil. Soil contained

2200 mg/kg mineral oil (generally at greater retention times than wax components, based on chromatograms provided in report), and was a sandy loam comprising 68% sand, 14.2% clay and 10.2% silt with 5.4% OC. Elevated levels of heavy metals were measured in the soil but not considered to be inhibitory to the test. Soil was suspended in mineral medium prior to distribution to test vessels at a loading rate of approximately 80 mg/l. No microbial enumeration was undertaken but performance of the inoculum in degrading a reference standard (sodium acetate at 100 mg/l) provided evidence of inoculum adequacy.

Concentration of test chemical: Test substance loading was approximately 20 mg/l of medium.

Temp of incubation: 20 ±2ºC

Dosing procedure: Each 2-liter vessel contained 1 liter of inoculated medium. The wax was dissolved in heated carbon tetrachloride, then the solution applied to glass fiber filters (13 mm) to obtain about 20 mg wax/filter after evaporation of the solvent. One filter was added to each test material vessel. Controls and reference standards also received glass fiber filters to which CCl_4 was added and allowed to evaporate.

Sampling frequency: Carbon dioxide production was monitored weekly through day 28, and then every other week to day 84. Wax residues were measured only at test termination.

Controls: Yes (blank and positive controls per guideline); abiotic and toxicity checks were not included. Sodium acetate was used as the positive control.

Analytical method: Carbon dioxide production was measured by titrating residual base with 0.1 N HCl. Wax residues were measured by extracting filters with warm heptane and the volume of extract adjusted prior to GC-FID analysis.

Method of calculating biodegradation: Wax was assumed to have a mean composition of [CH_2] for the purpose of calculating ThCO_2 (3.14 mg CO_2/mg wax). The report does not include the mechanics of calculation of the mineralization endpoint. Total hydrocarbon remaining at 84 days was determined by area integration of the chromatograms, and primary biodegradability was determined by comparing the amount of hydrocarbons at the end of the test with the amount on wax-dosed filters prepared at the start of the test.

Other: Two grades of paraffin wax, 52/50 and 58/60 were tested; only the 52/50 grade was tested for 84 days, and in all, three tests were carried out for 52/50. Result below for 28 days is mean of 52/50 average and 58/60 result. An intermediate wax was also tested as noted in results.

Test substance was incubated in the inoculated mineral

medium in sealed vessels containing a vial of 0.4 M NaOH (5 ml) suspended in the headspace above the medium (similar to EPA 835-3100). Carbon dioxide evolution resulting from mineralization of the test substance was trapped in the base for periodic quantitation. Base was renewed at each sampling period. GC analysis for parent compound was carried out on the solid phase of the test medium at study termination.

Reliability : (2) Valid with restrictions

(30)

Type : Aerobic
Inoculum : Oil-contaminated soil from land-farming project
Contact time : 84 day(s)
Result : Inherently biodegradable
Method : Modified OECD 301B (significant modification)
Year : 1989
GLP : Yes
Test substance : Microcrystalline wax CAS 63231-60-7

Remark : Wax residue analysis showed 65% parent hydrocarbons (mostly n-alkanes greater than C43) remained after 84 days. Most iso-alkanes were degraded regardless of carbon number.

Result : Degradation % after time: 21% of $ThCO_2$ after 28 days; 25% after 84 days

Kinetic (for sample, positive and negative controls:
Reference (sodium acetate) -Not Reported
Test substance - 21% (28d)

Breakdown Products: None

Test condition : Inoculum: Soil was collected from land-farm used by the investigators to treat oil-contaminated soil. Soil contained 2200 mg/kg mineral oil (generally at greater retention times than wax components, based on chromatograms provided in report), and was a sandy loam comprising 68% sand, 14.2% clay and 10.2% silt with 5.4% OC. Elevated levels of heavy metals were measured in the soil but not considered to be inhibitory to the test. Soil was suspended in mineral medium prior to distribution to test vessels at a loading rate of approximately 80 mg/l. No microbial enumeration was undertaken but performance of the inoculum in degrading a reference standard (sodium acetate at 100 mg/l) provided evidence of inoculum adequacy.

Concentration of test chemical: Test substance loading was approximately 20 mg/l of medium.

Temp of incubation: 20 ± 2ºC

Dosing procedure: Each 2-liter vessel contained 1 liter of inoculated medium. The wax was dissolved in heated carbon tetrachloride, then the solution applied to glass fiber filters (13 mm) to obtain about 20 mg wax/filter after evaporation of the solvent. One filter was added to each test material vessel. Controls and reference standards also received glass fiber filters to which CCl_4 was added and

allowed to evaporate.

Sampling frequency: Carbon dioxide production was monitored weekly through day 28, then every other week through day 84. Wax residues were measured at test termination.

Controls: Yes (blank and positive controls per guideline); abiotic and toxicity checks were not included. Sodium acetate was used as the positive control.

Analytical method: Carbon dioxide production was measured by titrating residual base with 0.1 N HCl. Wax residues were measured by extracting filters with warm heptane and the volume of extract adjusted prior to GC-FID analysis.

Method of calculating biodegradation: Wax was assumed to have a mean composition of [CH_2] for the purpose of calculating ThCO_2 (3.14 mg CO_2/mg wax). The report does not include the mechanics of calculation of the mineralization endpoint. Total hydrocarbon remaining at test termination was determined by area integration of the chromatograms, and primary biodegradability was determined by comparing the amount of hydrocarbons at the end of the test with the amount on wax-dosed filters prepared at the start of the test.

Other: Test substance was incubated in the inoculated mineral medium in sealed vessels containing a vial of 0.4 M NaOH (5 ml) suspended in the headspace above the medium (similar to EPA 835-3100). Carbon dioxide evolution resulting from mineralization of the test substance was trapped in the base for periodic quantitation. Base was renewed at each sampling period. GC analysis for parent compound was carried out on the solid phase of the test medium at study termination.

Reliability : (2) Valid with restrictions

(30)

Type : Aerobic
Inoculum : Naturally-occurring leaf-litter and soil biota (microbes and invertebrates)
Contact time : 6 month
Year : 1989
GLP :
Test substance : CAS 8002-74-2 and CAS 63231-60-7

Result : Decomposition in the 5 mm mesh bag, which were exposed to invertebrates as well as microbes, proceeded at a higher rate than in the 45 µm bags. Decomposition in the 5 mm mesh bags was nearly complete within 13 weeks in the autumn/winter test and within 26 weeks in the spring/summer test, while in the 45 µm bags 25 - 50% was still left after 6 months, based on visual observation. Wax residue analyses also indicated more rapid degradation in the cold-weather experiment.

Waxed and non-waxed (control) paper decomposed at the same rate.

Paraffin wax residue analysis showed after 6 months a complete or nearly complete degradation of the samples in the 5 mm mesh bags (the 52/54 paraffin wax showed 10% residues remaining after the spring/summer experiment and 0% after the autumn/winter experiment.

In the 45 µm bags, wax residues remaining at the end of the summer exposure were 30 - 50% for the paraffins and intermediate wax, and 60% for the microcrystalline wax. After winter exposure, paraffin wax residues were 10 - 30% of initial, intermediate wax is reported as 80% of initial, and microcrystalline wax residues were 40% of initial. The winter value for the intermediate wax appears incorrect based on the chromatograms, which show smaller peaks for the winter vs the summer analyses (same scale for both).

Test condition : Inoculum: Waxed paper was placed in nylon bags of different mesh size (45 µm or 5 mm) to allow colonization by either microbes alone or by microbes and soil fauna. Leaf litter served as the source of the inoculum, and was placed in a layer over the mesh bags at the start of the test.

Concentration of test chemical: Approximately 20 mg of wax per mesh bag.

Temp of incubation: Ambient forest litter layer temperatures. Testing was carried out during two different seasons: spring/summer (April - October 1989) and autumn/winter (November 1989 - May 1990)

Dosing procedure: Each mesh bag contained four 2 x 2 cm squares of waxed paper, which were dried and weighed before they were placed in the bags. The squares were arranged in a single layer within the bags (10 x 10 cm) to avoid sticking together.

Sampling frequency: Samples were retrieved monthly and decomposition of the squares was estimated visually. The remaining sample material was then removed from the bags, cleaned, dried (50 ºC) and weighed.

Controls: Non-waxed paper was used as a negative control.

Analytical method: 1) physical decomposition of paper: Each piece of paper was assessed visually according to the scale 100%, 75%, 50%, 25%, 5%, and 0% decomposition. 2) Wax residues were measured by extracting paper with warm heptane and the volume of extract adjusted prior to GC-FID analysis. To prevent interference of the analysis by the mesh bags, soil particles, and base paper, a cleanup step with aluminum oxide was used and as much of the bag material as possible was removed before extraction. The squares (or remnants thereof) from each treatment were pooled before extraction.

Method of calculating biodegradation: The extent of paper decomposition was determined by averaging the visual percent decomposition scores of the four squares. The degradation of

the wax was calculated from the analysis of samples taken at the start of the test, combined with analyses of uncoated paper and of field blanks for determination of background interference. Weight differences were not used as artifacts such as soil particles could not be removed from the waxed surfaces without removing the wax or destroying the paper.

Other: Two grades of paraffin wax, 52/50 and 58/60, intermediate wax, and microcrystalline wax were tested.

Conclusion : Waxed paper decomposes at about the same rate as unwaxed paper. Soil invertebrates contribute significantly to the decomposition of waxed paper in leaf litter. Decomposition of waxed paper occurs more rapidly during the autumn/winter, when there is a fresh layer of leaf litter on the ground, than during the spring/summer, when the last fall's leaf litter has been largely reduced to humus.

Reliability : (2) Valid with restrictions, since positive control data not reported (29)

Type : Aerobic
Inoculum : Unacclimated domestic sewage sludge supernatant and forest soil
Contact time : 137 day(s)
Deg. product : No
Method : Shake flask test
Year : 1989
GLP : No data
Test substance : Paraffin wax CAS 8002-74-2

Result : Degradation % after time: 55 % of $ThCO_2$ after 31 days; 98.5% after 137 days

Kinetic (for sample, positive and negative controls):
Reference (cellulose) 88.7% after 31 days
Test substance - 55% (31d); 98.5% (137 d)

Test condition : Inoculum: Soil was collected from a state park in central NJ, and sewage sludge was obtained from a domestic sewage treatment plant in Pennington, NJ. The sludge was aerated for 30 minutes and allowed to settle for an additional 30 minutes before the supernatant was withdrawn and filtered through #1 filter paper prior to use as the sewage inoculum. Filtrate was used at a rate of 25 ml/l of test medium (2.5%). Soil was added directly to each test flask at a rate of 0.1 g/l.
Concentration of test chemical: Test substance loading was approximately 10 mg carbon/l of medium.

Temp of incubation: 25 ± 2 ºC

Dosing procedure: Test material was added by direct addition of 11.8 mg grated wax to each test flask. Reference material (cellulose) was also weighed (25 mg) and added to the reference flasks to provide 10 mg C/l.

Sampling frequency: Carbon dioxide production was monitored after 2, 4, 7, 10, 17, and 24 days, and approximately weekly thereafter through day 137.

Controls: Yes (blank and positive controls per guideline); abiotic and toxicity checks were not included. Cellulose was used as the positive control.

Analytical method: Carbon dioxide produced by mineralization of the test substances was absorbed in 0.2 N KOH solution in cuvettes in the headspace of the test vessels. CO_2 production was measured by titrating residual base with 0.2N HCl.

Method of calculating biodegradation: Wax was assumed to contain 85% carbon for the purpose of calculating $ThCO_2$ wax). Average titration volumes at each sampling point were corrected for average blank volumes and then the amount of carbon dioxide produced was divided by $ThCO_2$ to determine percent biodegradation.

Conclusion : Not readily biodegradable; inherently biodegradable and extensively biodegradable in long-term exposures

Reliability : (2) Valid with restrictions. Unable to determine GLP status. Study report is in the form of a memo from which some details are lacking. Same details (e.g., temperature log) are also lacking from the raw data provided with the report
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(5)

Type : Aerobic
Inoculum : Unacclimated domestic sewage sludge supernatant and forest soil
Contact time : 137 day(s)
Result : Extensively biodegraded in long-term test
Deg. product : No
Method : Shake flask test
Year : 1989
GLP : No data
Test substance : Microcrystalline wax CAS 63231-60-7

Result : Degradation % after time: 27 % of $ThCO_2$ after 31 days; 67.2% after 137 days

Kinetic (for sample, positive and negative controls):
Reference (cellulose) 88.7% after 31 days
Test substance - 27% (31d); 67.2% (137 d)

Test condition : Inoculum: Soil was collected from a state park in central NJ, and sewage sludge was obtained from a domestic sewage treatment plant in Pennington, NJ. The sludge was aerated for 30 minutes and allowed to settle for an additional 30 minutes before the supernatant was withdrawn and filtered through #1 filter paper prior to use as the sewage inoculum. Filtrate was used at a rate of 25 ml/l of test medium (2.5%). Soil was added directly to each test flask at a rate of 0.1 g/l.
Concentration of test chemical: Test substance loading was approximately 10 mg carbon/l of medium.

Temp of incubation: 25 ± 2 ºC

Dosing procedure: Test material was added by direct addition

of 11.8 mg grated wax to each test flask. Reference material (cellulose) was also weighed (25 mg) and added to the reference flasks to provide 10 mg C/l.

Sampling frequency: Carbon dioxide production was monitored after 2, 4, 7, 10, 17, and 24 days, and approximately weekly thereafter through day 137. Controls: Yes (blank and positive controls per guideline); abiotic and toxicity checks were not included. Cellulose was used as the positive control.

Analytical method: Carbon dioxide produced by mineralization of the test substances was absorbed in 0.2 N KOH solution in cuvettes in the headspace of the test vessels. CO_2 production was measured by titrating residual base with 0.2N HCl.

Method of calculating biodegradation: Wax was assumed to contain 85% carbon for the purpose of calculating $ThCO_2$ wax). Average titration volumes at each sampling point were corrected for average blank volumes, then the amount of carbon dioxide produced was divided by $ThCO_2$ to determine percent biodegradation.

Reliability : (2) Valid with restrictions. Unable to determine GLP status. Study report is in the form of a memo from which some details are lacking. Same details (e.g., temperature log) are also lacking from the raw data provided with the report
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(5)

Inoculum : Activated sludge, domestic
Contact time : 28 day(s)
Method : OECD Guide-line 301 F "Ready Biodegradability: Manometric Respirometry Test"
Year : 1995
GLP : Yes
Test substance : Slack wax (petroleum), hydrotreated CAS 92062-09-4

Result : By day 28, 40% degradation of the test material was observed and indicated that the test material was inherently biodegradable. By day 5, >60% biodegradation of positive control was observed, which meets the guideline requirement. No excursions from the protocol were noted.Biodegradation was based on net oxygen consumption and the theoretical oxygen demand of the test material as calculated using results of an elemental analysis of the test material.

Sample	% Degradation* (day 28)	Mean % Degradation (day 28)
SN 60	50.20, 34.54, 33.92	39.55
Na Benzoate	82.04; 72.88	77.46

* replicate data

Test condition : Fresh activated sludge was obtained one day prior to test initiation, and homogenized in a blender for two minutes.
After allowing the sample to settle for approximately 30 minutes, the homogenated supernatant was decanted, avoiding carry-over of solids. Microbial activity of an aliquot of the filtered supernatant was $1E^6$ CFU/ml

which was determined using microbial agar dip slides. Activated sludge supernatant was added to the test medium at 10 ml/l, and the inoculated medium was continuously aerated with CO_2-free air until the next day when the test systems were prepared.
Test medium consisted of glass distilled water and mineral salts (phosphate buffer, ferric chloride, magnesium sulfate, calcium chloride). Test vessels were 1L glass flasks located in a waterbath and electronically monitored for oxygen consumption. Test material was tested in triplicate, controls and blanks were tested in duplicate. Test material (Slack wax (petroleum), hydrotreated) concentration was approximately 37 mg/l, equivalent to a theoretical oxygen demand (ThOD) of 127 mg/l. Test material was weighed onto a Gelman type A/E 13 mm glass fiber filter, which was then added to each respirometer flask. Sodium benzoate (positive control) concentration was 53.54 mg/l, and was added using an aliquot of a stock solution.
Test temperature was 22 ±1 °C. All test vessels were stirred constantly for 28 days using magnetic stir bars and plates.

Remark Although this specific slack wax process stream is not among the HPV-sponsored materials in this category, the hydrotreating procedure (i.e., removal of sulfur) does not substantially alter the component hydrocarbon character from the source slack wax material (CAS No. 64742-61-6).

Reliability : (1) Valid without restriction

(25)

Type : Aerobic
Inoculum : Domestic sewage, non-adapted
Concentration : 20 mg/l related to Test substance
Method : OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO2 evolution)"
Year : 1984
GLP : No data
Test substance : Two materials were tested
White mineral oil CAS 8042-47-5
Technical white oil CAS 8042-47-5
The test materials were not characterized any further
Remark : To assist in the evaluation of petrolatum and slack waxes, information on two white oils is included in this robust summary
Result : Degradation after 28 days was
0% for the white oil
24% for the technical white oil

(6) (45)

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type : Semistatic
Species : *Oncorhynchus mykiss* (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
Analytical monitoring : Yes
Method : OECD Guide-line 203 "Fish, Acute Toxicity Test"
Year : 1990
GLP : Yes
Test substance : Various lubricating base oils

Remark : Information on base oils is included here because the materials have similar hydrocarbon ranges and also have some structures in common with waxes. Hence the toxicity to freshwater fish of substances in the waxes category is expected to be similar to the lubricating base oils illustrated herein. Data presented below were selected from the base oil database because they were from highly reliable studies and represented the results of all other base oil testing with fish.
These, and more data have been summarized also in the robust summary for Lubricating Oil Basestocks

Result : All studies in the table below were conducted using *Oncorhyncus mykiss*

Base oil	Exposure method*	Endpoint**	Value (mg/l)
light paraffinic distillate			
	OWD	LL_{50}	>1 000
heavy paraffinic distillate			
	OWD	LL_{50}	>1 000
residual oil			
	OWD	LL_{50}	>1 000

* OWD=Oil-Water Dispersion

Test condition : Robust summaries of reports of multiple studies on the acute toxicity of lubricating base oils to fish, invertebrates and algae cited in the CONCAWE (1997) document have been prepared for the Lubricating Base Oils test plan. Those studies for which the results of invertebrate acute studies are given above were conducted under GLP and employed test conditions consistent with OECD guideline requirements.

Test substance : CAS 64741-89-5 solvent refined, light paraffinic distillate
CAS 64741-88-4 solvent refined heavy paraffinic distillate
CAS 64742-01-4 solvent refined residual oil

Reliability : (2) Valid with restrictions
Results of guideline studies provided in a reliable review dossier

(14)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type : Semistatic
Species : *Daphnia magna* and *Gammarus pulex*
Unit : mg/l
Analytical monitoring : Yes
Method : OECD Guide-line 202
GLP : Yes
Test substance : Lubricating base oil CAS 64741-97-5, solvent refined light naphthenic distillate

Remark : Information on base oils is included here because the materials have similar hydrocarbon ranges and also have some structures in common with waxes. Hence the toxicity to aquatic invertebrates of substances in the waxes category is expected to be similar to the lubricating base oils illustrated herein. Data presented below were selected from the base oil database because they were from highly reliable studies and represented the results of all other base oil testing with aquatic invertebrates.
These, and more data have been summarized also in the robust summary for Lubricating Oil Basestocks

Result : Results for a Solvent refined, light naphthenic distillate
These data, originating from Shell, are summarized in CONCAWE (1997).

Test species	Exposure method	Endpoint	Value (mg/l)
Daphnia magna	WAF*	EL_{50}	>10 000
Gammarus pulex	WAF	EL_{50}	>10 000

* WAF = Water Accommodated Fraction

Test condition : Robust summaries of reports of multiple studies on the acute toxicity of lubricating base oils to fish, invertebrates and algae cited in the CONCAWE (1997) document have been prepared for the Lubricating Base Oils test plan. Those studies for which the results of invertebrate acute studies are given above were conducted under GLP and employed test conditions consistent with OECD guideline requirements.

Reliability : (2) Valid with restrictions
Results of guideline studies provided in a reliable review dossier
(14)

Type : Static and semi-static tests
Species : *Daphnia magna, Chaetogammarus marinus* and *Mysidopsis bahia*
Exposure period :
Unit : mg/l
Analytical monitoring : Yes
Method : Not stated
Year : 1986
GLP : No
Test substance : Various paraffin hydrocarbons, C5 to C14, normal, iso- and cyclo structures

Method : Statistical method: $L(E)C_{50}$ by Kooijman (1981)

[Kooijman, S. A. L. M. (1981)

Parametric analyses of mortality rates in bio-assays.
Water Res. Vol 17, pp 107-119]

Remark : Analytical measurements of test substance concentrations in the exposure solutions were not provided by the authors for each exposure level. Rather, the authors listed data for the test levels near the $L(E)C_{50}$ value. Results show that in spite of preparing test solutions and testing in sealed vessels, initial concentrations typically did not achieve the theoretical solubility limit and tended to decline between 0-hour and 24/48 hour measurements.

Result : Tests were conducted multiple times, and the following L(E)C50 values are either means and 95% confidence intervals of the number of tests indicated, or results of limit tests that were conducted.

Test Compound	S1 mg/l	Nominal Conc. $L(E)C_{50}$, mg/l (# tests) (95% confidence intervals) *D. magna*	*C. marinus*	*M. bahia*
pentane	38	9.1 (4) (8.5-9.7)	10.5 (3) (9.5-11.6)	10.2 (3) (9.3-11.2)
isopentane	NG2	~3 4.2 (2)	~10 (2)	~10 (2)
n-hexane	9.5[4]	3.2 (4) (3.0 - 3.4)	--	--
isohexane	~13	~4.2 (3)	~4.2 (1)	~4.2 (1)
cyclohexane	55	~2.4 (3)	3.1 (1) (0.1 - 7.8)	3.1 (1) (1.0 - 9.8)
n-heptane	2.7	3.9 (4) (3.7 - 4.2)	3.1 (1) (1.0 - 9.4)	2.1 (1) (1.7 - 2.5)
cycloheptane	NG	0.74 (4)	~1.4 (1)	~1.4 (1)
n-octane	0.66	~S (1)	~S (5)	~S (5)
iso-octane	NG	~2.4 (2)	5.4 (1) (4.3 - 6.7)	2.4 (1)
n-nonane	~0.2	~S (6)	~S (3)	>S (3)
n-decane	0.05	>S (6)	>S (2)	>S (2)
n-undecane	NG	>S	>S (1)	>S (1)
n-dodecane	0.004	>S	>S (1)	>S (1)
n-tridecane	NG	>S	>S (1)	>S (1)
n-tetradecane	0.002	>S	>S (1)	> S (1)

1 S = solubility.
2 NG = Not Given.
3 ~ indicates approximate value.
4 + indicates equal to or greater than.

Test condition : All test solutions were prepared separately by the addition of the nominal amount of test substance to dilution water in a conical flask. Flasks were filled nearly to capacity (minimal headspace), capped with a glass stopper and then stirred for 24 hours with a magnetic stirrer. After stirring, the solutions were permitted to stand for either 4 or 24 hours, and the test solutions were decanted from the bottom of the flask into the test vessels.

Vessels for testing daphnids were 250-ml conical flasks and held 25 daphnids during testing. Flasks were completely filled with test solution (no headspace) and closed with glass stoppers to prevent volatilization. Vessels for testing the gammarids and mysids were 20-ml scintillation vials and each vial held one gammarid or one mysid during testing. Ten vials were used for each test solution. Vials were completely filled with test

solution (no headspace) and capped to prevent volatilization. Tests with daphnids were not renewed during the 48-hour exposure, but tests with gammarids and mysids were renewed with freshly-prepared exposure solutions every 24 hours.

All test animals were cultured in the laboratory; *C. marinus* used in testing were young, approximately 5 mm long; *M bahia* were approximately 4 weeks old and 6 mm long; and *D. magna* were <24 hours old. Testing was conducted at 20 °C. *C. marinus* and *M. bahia* were tested in natural seawater, while *D. magna* were tested in synthetic freshwater medium having a hardness of approximately 210 mg/l as $CaCO_3$ and a pH ranging from 8.0 to 8.2. Water pH and dissolved oxygen concentrations were monitored during testing (frequency not stated). The article states that the pH values in all the tests ranged from 7.5 to 8.3, and dissolved oxygen concentrations were always >6.5 mg/l.

Analytical determinations of test substance concentrations were made by gas chromatography with an apolar capillary column and flame ionization detector. Identification of specific compounds was made by retention times. Measurements of test substance concentrations were made on samples taken from the *D. magna* tests at 0-hours (fresh solutions) and 48-hours (old solutions). Solutions analyzed in the *C. marinus* and *M. bahia* tests were taken at 0-hours (fresh) and 24 hours (old). Not all analytical results were quoted, but those closest to the $L(E)C_{50}$ value were provided and used to calculate "initial concentration" $L(E)C_{50}$ values. Therefore, these were considered by the author to be rough estimates. The values reported below by the author were based on nominal concentrations.

Reliability : (2) Valid with restrictions
Well-documented publication which meets basic scientific principles

(4)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species	:	*Scenedesmus subspicatus* (Algae)
Exposure period	:	96 hour(s)
Unit	:	mg/l
Analytical monitoring	:	Yes
Method	:	OECD Guide-line 201 "Algae, Growth Inhibition Test"
Year	:	1990
GLP	:	Yes
Test substance	:	Various lubricating base oils

Remark : Information on base oils is included here because the materials have similar hydrocarbon ranges and also have some structures in common with waxes. Hence the toxicity to algae of substances in the waxes category is expected to be similar to the lubricating base oils illustrated herein. Data presented below were selected from the base oil database because they were from highly reliable studies and represented the results of all other base oil testing with algae.
These, and more data have been summarized also in the robust summary for Lubricating Oil Basestocks

Result : All studies in the table below were conducted using *Scenedesmus subspicatus*

Base oil	Exposure method*	Endpoint**	Value (mg/l)
light paraffinic distillate			
	WAF	IrL50	>1 000
		IbL50	>1 000
heavy paraffinic distillate			
	WAF	IrL50	>1 000
		IbL50	>1 000
residual oil			
	WAF	IrL5050	>1 000
		IbL50	>1 000

* WAF = Water Accommodated Fraction

** IrL50 = Concentration that inhibits growth (rate) by 50%

IbL50 = Concentration that inhibits growth (biomass) by 50%

Test condition : Robust summaries of reports of multiple studies on the acute toxicity of lubricating base oils to fish, invertebrates and algae cited in the CONCAWE (1997) document have been prepared for the Lubricating Base Oils test plan. Those studies for which the results of invertebrate acute studies are given above were conducted under GLP and employed test conditions consistent with OECD guideline requirements.

Test substance : CAS 64741-89-5 solvent refined, light paraffinic distillate
CAS 64741-88-4 solvent refined heavy paraffinic distillate
CAS 64742-01-4 solvent refined residual oil

Reliability : (2) Valid with restrictions
Results of guideline studies provided in a reliable review dossier

(14)

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

Species : *Daphnia magna* (Crustacea)
Endpoint : Reproduction/survival
Exposure period : 21 day(s)
Unit : mg/l
Analytical monitoring : Yes
Method : OECD Guide-line 202, part 2 "Daphnia sp., Reproduction Test"
GLP : Yes
Test substance : Various base oils

Remark : Information on base oils is included here because the materials have similar hydrocarbon ranges and also have some structures in common with waxes. Hence the toxicity to aquatic invertebrates of substances in the waxes category is expected to be similar to the lubricating base oils illustrated herein. Data presented below were selected from the base oil database because they were from highly reliable studies and represented the results of all other base oil testing with aquatic invertebrates.
These, and more data have been summarized also in the robust summary for Lubricating Oil Basestocks

Result :

The NOEL for three base oils are shown in the following table

Test material	Exposure method	Value (mg/l)
Solvent refined, heavy paraffinic distillate		
	WAF	>1 000
Hydrotreated, light naphthenic distillate		
	WAF	>1
Solvent refined residual oil		
	WAF	>1 000

* WAF = Water Accommodated Fraction

** Value represents the no observable effect level (NOEL)

Test condition : Robust summaries of reports of multiple studies on the chronic toxicity of lubricating base oils to fish and invertebrates, cited in CONCAWE (1997), have been prepared for the Lubricating Base Oils test plan. Those studies for which the results of invertebrate chronic studies are given above were conducted under GLP and employed test conditions consistent with OECD guideline requirements.

Reliability : (2) Valid with restrictions
Results of guideline studies provided in a reliable review dossier

4.9 ADDITIONAL REMARKS

: **Comments relating to partition coefficient**

Remark : The values of log Kow for individual hydrocarbons increase with increasing carbon number within homologous series of generic types. Quantitative structure activity relationships (QSAR), relating log Kow values of single hydrocarbons to toxicity, show that water solubility decreases more rapidly with increasing Kow than does the concentration causing effects (Abernathy, et al, 1988; Donkin, et al, 1991). This relationship varies somewhat with species, but it follows that there is a log Kow limit for hydrocarbons, above which, they will not exhibit acute toxicity; this limit is at a log Kow value of about 4 to 5 (Abernathy, et al, 1988; Donkin, et al, 1991). It has been confirmed experimentally that for fish and invertebrates, paraffinic hydrocarbons with a carbon number of 10 or higher (log Kow >5) show no acute toxicity (Adema, 1986) and that alkylbenzenes with a carbon number of 14 or greater (log Kow >5) similarly show no acute toxicity (Adema, 1991) From these well-demonstrated solubility 'cut-offs' for acute toxicity of hydrocarbon substances, which directly relate to their physico-chemical properties, it is clear that the same should hold for complex petroleum substances. QSAR equations for chronic toxicity also suggest that there should be a point where

hydrocarbons with high log Kow values become so insoluble in water that they will not cause chronic toxicity, that is, that there is also a solubility cut-off for chronic toxicity (McCarty, L.S. et al, 1991; European Union,1996). Thus, paraffinic hydrocarbons with carbon numbers of greater than 14 (log Kow >7.3) should show no measurable chronic toxicity. The existence of this cut-off for chronic toxicity is supported for petroleum substances by the numerous chronic toxicity studies reported on lubricant base oils, which demonstrate that for these substances which are composed primarily of alkanes and naphthenes of C15 and greater, no evidence of chronic toxicity is seen (CONCAWE, 1997). Further evidence to support this generalisation is provided by a lack of chronic toxicity for hydrocarbon based solvents (CEFIC, 2000)
Representative chronic aquatic toxicity data for selected base oils presented in the CONCAWE (1997) review are summarized in 4.5.2 above
(1) (3) (4) (11) (14) (19) (22) (42)

: **Comments relating to physical size and number of carbon atoms in waxes and related materials**

Remark : The physical size and number of carbon atoms in petroleum waxes and related materials severely limits the ability of these materials to be taken up into living organisms. It is accepted that the ecotoxicity of alkanes of carbon number greater than C10 are not acutely toxic to aquatic organisms at their limit of solubility in water (Adema, 1986). The petroleum waxes, containing hydrocarbons greater than C13, would not be expected to cause acute toxicity to aquatic organisms.
The results of toxicity tests with lubricant base oils, which have similar hydrocarbon ranges and some structures in common [Sections 4.1., 4.2. and 4.3. above], show no acute toxicity to freshwater fish, invertebrates, or algae and no chronic effects to aquatic life at concentrations below 1 mg/l. (CONCAWE, 1997, 2001)
(4) (14) (16)

: **Comments relating to slack wax**

Remark : In February of 2001 discharge of slack wax to national parks along British Columbia (Canada) coastline occurred during tank washing activities, impacting approximately 100 km of Pacific Rim National Park beach. Canadian Wildlife Service (a branch of Environment Canada) and the Department of Fisheries and Oceans biologists agreed that the risk of acute toxicity to aquatic life in the area was minimal based on the low solubility of the components in the wax and given that the BC Parks staff observed no significant environmental impacts. Generally the consensus was that the material was relatively inert and would likely pose little environmental damage.

(24)

5.1.1 ACUTE ORAL TOXICITY

Type	:	LD_{50}
Value	:	> 5000 mg/kg bw
Species	:	Rat
Strain	:	No data
Sex	:	Male/female
Number of animals	:	10
Vehicle	:	Arachis oil
Year	:	1976
GLP	:	No data
Test substance	:	R 9071 is described as paraffin wax, without further characterization. R 9071 was prepared as solutions in arachis oil for oral dosing. Two concentrations (20 and 100 mg/ml) were prepared for the two dose levels tested.
Method	:	Paraffin wax was administered orally as a solution in arachis oil to groups of 5 male and 5 female rats at dose levels of 1 and 5 g/Kg. The rats were observed for clinical signs of toxicity for the following 7 days. On the seventh day the animals were weighed, then killed and autopsied.
Result	:	There were no clinical signs of toxicity during the seven day observation period and growth rates were normal. There were no mortalities and no macroscopic changes were observed at autopsy. The LD_{50} was found to be greater than 5g/Kg.
Reliability	:	(1) Valid without restriction. Although there is no indication that the study was carried out according to GLP, it nevertheless is a reliable study and full details are provided in the laboratory report.

(34)

Type	:	LD_{50}
Value	:	> 5000 mg/kg bw
Species	:	Rat
Strain	:	No data
Sex	:	Male/female
Number of animals	:	10
Vehicle	:	Arachis oil
Year	:	1976
GLP	:	No data
Test substance	:	R 9269 is described as microcrystalline wax, without further characterization. R 9269 was prepared as solutions in arachis oil for oral dosing. Two concentrations (20 and 100 mg/ml) were prepared for the two dose levels tested.
Method	:	Microcrystalline wax was administered orally as a solution in arachis oil to groups of 5 male and 5 female rats at dose levels of 1 and 5 g/Kg. The rats were observed for clinical signs of toxicity for the following 7 days. On the seventh day the animals were weighed, then killed and autopsied.
Result	:	There were no clinical signs of toxicity during the seven day observation period and growth rates were normal. There

were no mortalities and no macroscopic changes were observed at autopsy.
The LD_{50} was found to be greater than 5g/Kg.

Reliability : (1) Valid without restriction.
Although there is no indication that the study was carried out according to GLP, it nevertheless is a reliable study and full details are provided in the laboratory report.

(35)

5.1.3 ACUTE DERMAL TOXICITY

Type	:	LD_{50}
Value	:	> 4000 mg/kg bw
Species	:	Rabbit
Strain	:	No data
Sex	:	No data
Vehicle	:	Petrolatum
Year	:	1972
GLP	:	No
Test substance	:	Paraffin wax administered as a 50% solution in petrolatum
Method	:	Method is not described.
Remark	:	The report does not provide sufficient information to fully evaluate the study.
Reliability	:	(4) Not assignable This information is taken from a published safety review conducted by an expert panel. Few experimental details are provided and the quality of the studies and the panel's conclusions cannot be verified.

(21)

5.2.1 SKIN IRRITATION

Species	:	Rabbit
Concentration	:	Undiluted
Exposure	:	Occlusive
Exposure time	:	24 hour(s)
Number of animals	:	9
Result	:	Not irritating
Year	:	1984
GLP	:	No data
Test substance	:	Paraffin wax and Microcrystalline wax
Remark	:	An expert panel on cosmetics reviewed the skin irritation data and reported: * An undiluted paraffin wax was non-irritant in a 24 hour occluded patch test in rabbits * A microcrystalline wax was slightly irritating in a 24 hour occluded patch test
Result	:	The report contains the following statement: A sample of 100% paraffin wax was applied full strength under a single closed patch to the skin of 9 rabbits. No irritation developed.

Three samples of 50% paraffin in petrolatum were tested in repeated, open patch applications to 6 rabbits. Two samples produced erythema in four animals that lasted three days, and one produced erythema in one rabbit that lasted two days.
No other details are provided.

Reliability : (4) Not assignable.
This information is taken from a published safety review conducted by an expert panel. Few experimental details are provided and the quality of the studies and the panel's conclusions cannot be verified

(21)

5.2.2 EYE IRRITATION

Species	:	Rabbit
Concentration	:	50 %
Dose	:	0.1 ml
Exposure time	:	72 hour(s)
Comment	:	Not rinsed
Number of animals	:	6
Vehicle	:	Petrolatum
Result	:	Slightly irritating
Year	:	1984
GLP	:	No data
Result	:	The publication states: Four 50% solutions of paraffin in petrolatum were each instilled into the eyes of six albino rabbits with no rinse. Eyes were observed for irritation for three days. Two of the samples caused mild irritation in one rabbit on day 1; the other samples were not irritating.
Reliability	:	(4) Not assignable. This information is taken from a published safety review conducted by an expert panel. Few experimental details are provided and the quality of the studies and the panel's conclusions cannot be verified.

(21)

5.4 REPEATED DOSE TOXICITY

Species	:	Rat
Sex	:	Male/female
Strain	:	Fischer 344
Route of admin.	:	Oral feed
Exposure period	:	90 days
Frequency of treatm.	:	Continuous in food
Post exposure period	:	28 days
Doses	:	0.002, 0.02, 0.2 & 2.0% in the diet
Control group	:	Yes, concurrent no treatment
Method	:	OECD Guide-line 408 "Subchronic Oral Toxicity - Rodent: 90-day Study"
Year	:	1992
GLP	:	Yes

Test substance : This study was carried out on six mineral oils and three petroleum waxes (a paraffin wax and two microcrystalline waxes). Only information on the waxes is included in this robust summary. For additional details on the oils, see the Lubricating Oil Basestocks Test plan.

The waxes were:

Paraffin wax

LMPW A hydrotreated low melting point paraffin wax

Microcrystalline waxes

HSW A clay-treated microcrystalline wax (High Sulfur Wax)

HMPW Hydrotreated microcrystalline wax, high melting point (High Melting Point Wax)

The characteristics of the three waxes are as follows (CONCAWE, 1993)

Property	**Unit**	**Method (ASTM)**	**LMPW**	**HSW**	**HMPW**
Color		D1550	L0.5	L0.5	L0.5
Penetration at 25°C	0.1 mm	D1321	18	27	13
Penetration at 40°C	0.1 mm	D1321	83	101	29
Congealing point	°C	D938	53.5	74.5	85.0
Drop meltingpoint	°C	D127	55.6	82.0	91.4
Oil content	%	D721	0.1	1.8	1.3
Distillation ranges					
	°C	D86			
	5%		369	411	510
	50%		414	551	564
	95%		467	698	721
Viscosity at 100 °C	mm^2/s	D445	3.3	13.7	15.4
Density at 100 °C	kg/m^3	D1298	751.5	794.4	789.2
Ash content	%	D482	<0.01	0.01	<0.01
Refractive index at 100 °C		D1747	1.4230	1.4404	1.4393
Sulfur	ppm	D2622	5	2100	77
Acidity/alkalinity		USP XXIII	----------Pass----------		
UV absorbance		FDA 172.806	----------Pass----------		
Arsenic	ppm	AAS	<1	<1	<1
Chromium	ppm	AAS	<1	<1	<1
Cadmium	ppm	AAS	<1	<1	<1
Lead	ppm	AAS	<1	<1	<1

Method : The study consisted of three components each of which is described below.

Main study
Groups of 20 male and 20 female rats were fed diets containing one of three different waxes at dietary concentrations of 0.002, 0.02, 0.2 & 2.0 % for 90 days. Groups of 60 male and 60 females were fed untreated control diet for the same period of time.
A further group of 20 rats of each sex were fed diets containing 2.0 % coconut oil.

Reversal study
Groups of ten rats of each sex were fed diets containing each test material at the 2.0 % level or coconut oil at the 2 % level for 90 days, followed by a 28 day period on control diet. Groups of 300 rats of each sex were fed control diet for the same time period.

Tissue level and reversal study
Groups of ten rats of each sex were fed either control diet, or diet containing 2 % of each of the test materials or coconut oil at 2 % for 90 days. At the end of the 90-days, five rats of each sex were sacrificed and their tissues analyzed for mineral hydrocarbons. The remaining five animals of each sex were then fed control diet for a further 28 days, at the end of which they also were sacrificed and their tissues analyzed for mineral hydrocarbons.

The entire study consisted of 40 different treatment groups and their organization is summarized in the following table.

Group	Treatment*	Main M/F	Reversal M/F	Tissue level and reversal M/F
1	Control	20/20	10/10	10/10**
2	Control	20/20	10/10	
3	Control	20/20	10/10	
4-27 incl.	groups fed diets containing the mineral oils			
28	LMPW (0.002%)	20/20	10/10	10/10
29	LMPW (0.02%)	20/20	10/10	
30	LMPW (0.2%)	20/20	10/10	
31	LMPW (2.0%)	20/20	10/10	
32	HMPW (0.002%)	20/20	10/10	10/10
33	HMPW (0.02%)	20/20	10/10	
34	HMPW (0.2%)	20/20	10/10	
35	HMPW (2.0%)	20/20	10/10	
36	HSW (0.002%)	20/20	10/10	10/10
37	HSW (0.02%)	20/20	10/10	
38	HSW (0.2%)	20/20	10/10	
39	HSW (2.0%)	20/20	10/10	
40	Coconut oil (2.0%)	20/20	10/10	10/10

* For a description of each wax see "test substance" section

** 5 animals were for tissue level analysis after 90 days and five were for tissue level after a 28 day reversal period.

All animals were monitored for weight, food intakes and clinical condition throughout the study. An ophthalmic examination was performed prior to treatment and prior to necropsy on the animals in the main study and those for the study of reversibility.

Necropsy

Main study and reversal animals

A full necropsy was performed and any abnormalities were recorded. The following organs were weighed:
adrenal glands
brain
caecum (with and without contents
heart
kidney
liver ovaries
spleen
testes
thymus.

Samples of the following tissues were fixed for subsequent microscopic examination:
adrenal glands, artery (aorta), bladder, brain, caecum, colon, cervix uteri, diaphragm, duodenum, epididymis, extra orbital lachrymal glands, eye, femur, Harderian gland, heart, ileum (including Peyer's patches), jejunum, kidneys, liver (representative samples from each lobe), lungs, (with main stem bronchi), lymph nodes (axillary, cervical & mesenteric), mammary gland (inguinal region), nasal bones, nerve (sciatic taken together with surrounding muscle), oesophagus, ovaries, pancreas, perirenal fat, pinnae (retained for identification only), pituitary, prostate, rectum, salivary gland, seminal vesicles, skeletal muscle, skin (inguinal region), spinal cord, spleen, sternum, stomach, testes, thymus, thyroid/parathyroid glands (retained on trachea), tongue, uterine horns, vagina and vein (posterior vena cava).
In addition, samples of the following tissues from the high dose and control animals only were retained in formol calcium: liver, spleen, small intestine & mesenteric lymph node.

Histological examination of tissues
A microscopic examination was made of H&E sections of all preserved tissues from the control and high dose group and from the lung, liver, kidney, spleen, small intestine and mesenteric lymph node of all other groups. All lung sections were examined for evidence of infection.

Hematology
Blood samples collected from all animals on the main study

and the reversal study were examined for: total erythrocyte count, total leucocyte count, hemoglobin concentration, mean cell volume, hematocrit (by calculation), platelet count, differential leucocyte count, reticulocyte count and prothrombin time.

Clinical chemistry
Serum from main and reversal study animals was examined for: concentrations of glucose, urea, total protein, albumin, creatinine, calcium, phosphorus (as phosphate), chloride, total bilirubin, sodium and potassium. Activity of the following enzymes was also determined: alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase and gamma glutamyl transferase.

Tissue level and tissue level reversal animals
Animals designated to provide tissues for analysis for mineral hydrocarbons were killed and the following tissues weighed and taken for analysis:
Liver (random samples from the periphery of all lobes)
Mesenteric lymph nodes (all tissue)
Kidney (one kidney)
Spleen (approximately half)
Perirenal fat (random sample)

Tissue analysis for mineral hydrocarbon content
Tissue samples (approximately 1 g of tissue) from those animals designated for tissue analysis were homogenized in 70 % KOH solution. The homogenate was sonicated for 10 minutes at 60 °C. CCl_4 was added to each sample and sonicated for 30 minutes, also at 60 °C, occasionally mixing by hand. The layers were separated using centrifugation if necessary.
An aliquot of the lower organic phase was poured onto an extraction column (Florosil) and the eluate was collected and the column washed with CCl_4 to a known final volume. The infra-red absorbance, in the C-H stretching region, of the eluate was measured against a CCl_4 background using a Fourier Transform infra-red spectrometer. The concentration of mineral hydrocarbon in the tissue was calculated by comparison with appropriate standards.

Statistical analysis
The continuous variable data from the control and test groups were tested for normality using the Kolmogorov-Smirnov (K.S.) test and homogeneity of variance using Bartlett's test.
Statistical significance was determined to be at $p<0.05$ in a K.S. test and at $p<0.01$ in a Bartlett's test. If both tests were non significant, the control and test groups were compared using analysis of variance followed by the least significant difference (L.S.D.) test.
If either test produced a significant result, a suitable transformation was attempted. If the transformation data resulted in a non-significant Bartlett's test but a

significant K.S. test, the Wilcoxon Mann-Whitney test was used. If the transformed data resulted in a non-significant K.S. test but a significant Bartlett's test, an appropriate t-test was used, based on whether a pooled variance was suitable or not.
If no suitable transformation could be made, one of the above tests was selected as the most appropriate based on the nature and distribution of the data.
Where levels of significance were reported in the tables for transformed data the means and standard deviations were reported for the untransformed data.
The results of the Mann-Whitney and t-tests were compared with the L.S.D. test. In most cases, the L.S.D test was reported. However, if large differences were evident, other test results were reported as appropriate unless the data was deemed to be highly variable and there was no evidence to justify the removal of outliers.
Incidence data from the histopathogical examination was tested for differences between treated and control animals using Fischer's exact test. Mann-Whitney tests were performed on incidence data graded by severity.
In all test comparisons, a probability level of $p<0.05$ in a two sided test was taken to indicate statistical significance.

Result : **Main study**

Microcrystalline waxes (HSW and HMPW)

Growth rates, food intakes and clinical condition of animals fed either HSW or HMPW were unaffected by exposure
No effects were observed at necropsy for either test material.
Although there were minor organ weight changes, the authors did not consider them to be treatment-related unless a dose-related trend was apparent. The % increases (+%) or decreases (-%) at the various dietary concentrations are summarized below:

	Dietary concentration (%)			
Treatment	**0.002**	**0.02**	**0.2**	**2.0**
HMPW				
Abs. Male kidney	+5			
Rel. Male kidney	+4			
Abs. Male liver		+4		
Rel. Male liver		+3		
Abs. Female spleen		-5		
Rel. female spleen	-5			
HSW				
Abs. Female kidney	-3			
Rel. Male liver		+4	+3	
Rel. Female liver	-5			

The only minor hematological difference recorded was a 2% increase in hemoglobin concentration in males in the highest dose groups of both HSW and HMPW. Females were unaffected.

Serum glucose levels were raised in all dose groups of animals fed HMPW and in all but the highest dose group of animals fed HSW.
The % increases were:

Dietary concentration (%)	HMPW	HSW
0.002	13	9
0.02		8
0.2	10	11
2.0	8	

No treatment-related histological changes were observed in either the HSW or the HMPW group animals.

Main, reversal and tissue level studies
Paraffin wax (LMPW)

Although growth rates, food intakes and clinical condition of animals fed LMPW were unaffected by exposure, there was a spectrum of changes that occurred as follows.
Organ weight changes were recorded in both sexes. Liver and spleen weights (absolute & relative) were increased at the 2 and 0.2% dose levels. Although some reduction was observed after the reversal period in the 2% dose groups, they were still higher than the corresponding controls.
Mesenteric lymph node weights were only available for the high dose level animals and these were increased following exposure to LMPW. Although the lymph node weights had reduced in the reversibility group they had not returned to normal by the end of the reversibility period.
The % increase (+) or decrease (-) in the hematological parameters are shown in the following table. The statistical significance of the differences are also indicated
(* p<= 0.05, ** p<= 0.01, *** p<= 0.001).

Parameter	Dietary concentration (%) 0.002	0.02	0.2	2.0
Males				
RBC		+2*		
Hemoglobin		+2*	-2*	-2**
MCH			-2***	-2***
WBC	+16*	+20*	-3	+9
Neutrophils			+22**	+23**
Platelets	-3	-3	-7**	-13***
Females				
RBC				-4***
Reticulocytes				+43***
Hemoglobin content				-6***
Hematocrit				-4***
MCH				-2***
WBC			+26***	+48***
Neutrophils			+45***	+89***
Lymphocytes		+21*	+18*	+29***

Monocytes	+35**	+103***
Eosinophils		+41*
Basophils Actual value (Control value = 0)	0.003***	0.004***
Platelets	-14***	-16***

There were raised serum liver enzyme levels in the highest two dose groups of females but only at the highest dose in males. The enzymes affected were ALA, ALAT, ASAT and Gamma-GT. Serum bilirubin was also elevated in the highest dose group of females. Albumin/globulin ratios were reduced in the females at the highest 2 dose levels and in the highest dose level only for the males.

Histopathological lesions were observed in many tissues and were of a severity and nature consistent with the age of the animals and were not considered to be treatment-related. However lesions in the liver, mesenteric lymph node, Ileum & jejunum and heart were considered to be compound-related. These were as follows:

Liver
Granulomas were observed in the livers of male and female rats at the highest 2 dose levels. At the highest dose centrilobular vacuolation was also observed. After the one month reversal period, granulomas were still present at the same incidence but their severity was less.

Mesenteric lymph node
The lymph node lesions comprised focal collections of slightly vacuolated macrophages in the cortical region and after one month's reversal these were reduced in severity. Such lesions occurred to varying degrees of severity at all dose levels.

Ileum & jejunum
There was an increased incidence in macrophage accumulation in Peyer's Patches in both sexes at the highest two dose levels. There was also an increase in macrophage infiltration of the lamina propria in the high dose females.

Heart
A focal inflammatory lesion was observed within the cusps of the mitral valve. The lesion was characterised by an increased cellularity of the valve with destruction of the fibrous core. The lesion was observed in 11/20 males and 11/20 females at the highest dose level and 5/20 females at the 0.2% group. Following the 28 day reversal period there was still an increased incidence of the lesion but this was less than that at the end of the 90-day feeding study.

Analysis of tissues for mineral hydrocarbons.
In the tissue level studies, no mineral hydrocarbons were found in the kidneys of rats fed LMPW. However it was found in the perirenal fat, liver and lymph nodes.
After the 28-day reversal period, mineral hydrocarbon was still found in these tissues, albeit at lower concentrations.

No mineral hydrocarbons were found in any of the tissues of animals fed microcrystalline wax.

Remark : The purpose of this study was to investigate the biological effects of six mineral oils and three petroleum waxes representative of those used in food processing and food contact applications.
This robust summary only describes the results from the three petroleum waxes that were examined.
For additional details on the oils see the Lubricating Oil Basestocks Test Plan.

Reliability : (1) Valid without restriction.
Study conducted to GLP and thoroughly reported.

(8) (13)

Species : Rat

Remark : The purpose of this study was to assess the safety in use of a variety of oils and waxes for food contact applications.
As a follow up to this study, additional studies were carried out on other finished wax samples and the results are summarized in the table below.

The severity and incidence of the responses were related to the average molecular weights of the materials tested; the lower molecular weight materials causing the most severe effects (CONCAWE 1993).

Sample	Viscosity @ 100°C (cSt)	Carbon Chain Length	Average Mol. Weight	NOAEL (mg/kg/day)
LMPW	3.3	19-42	375	<2
Blend	8	19-80	470	<2
IMPW	6.3	21-49	480	<2
HSW	13.7	20-74	600	2000
HMPW	15.4	22-80	630	2000

LMPW: Low melting point finished wax
Blend: Blend of LMPW & HMPW
IMPW: Intermediate melting point finished wax
HSW: High sulfur wax
HMPW: High melting point finished wax

The findings from all the above studies allowed the EU Scientific Committee for Food (SCF 1995) to set ADIs for the high sulphur (HSW) and high molecular weight waxes (HMPW), but not for the lower molecular weight materials since for these NOELS had not been established.

A further study has also been carried out in which Low Melting Point Wax was fed to F-344 and Sprague Dawley rats at dietary concentrations of 0.2 and 2.0% in the diet for 90 days.

The findings in the F-344 rats were essentially similar to those found in the studies summarized above but the Sprague Dawley rat was found to be a less sensitive strain.

The only effects of treatment seen were an increase in mesenteric lymph node weight and microscopic findings in the same tissue (microgranulomas and reticuloendothelial cell hyperplasia). These effects were less severe and less frequent than those seen in the F-344 rats.

(9) (10)

5.5 GENETIC TOXICITY 'IN VITRO'

: No data available

5.6 GENETIC TOXICITY 'IN VIVO'

: No data available

5.7 CARCINOGENICITY

Species	:	Mouse
Sex	:	Male
Strain	:	C3H
Route of admin.	:	Dermal
Exposure period	:	80 weeks
Frequency of treatm.	:	Twice weekly
Doses	:	50 mg/application
Result	:	Negative
Control group	:	Untreated control and positive control (BaP)
GLP	:	No
Method	:	50 mg melted slack wax was painted on the skin of 50 individually housed male mice, twice weekly for 80 weeks. The animals were shaved bi-weekly with electric clippers and the test material applied to the shaven intrascapular region. Treatment was continued for 80 weeks. A concurrent negative untreated control and a positive control (benzo-a-pyrene) was included in the study. The study was repeated using 25 mg/application, twice weekly.
Remark	:	This report is a summary of results from an extensive program of studies. Consequently all the experimental details have not been presented. The authors state that such details are available in the original laboratory reports.
Result	:	No skin tumors developed in any of the mice to which slack wax had been applied in either of the studies. The responses in the control groups is not reported.
Test substance	:	Slack wax CAS No. 64742-61-6 The sample was tested twice in the study summarized by Kane et al.
Reliability	:	(2) Not assignable. The report summarizes data from many studies and does not contain sufficient detail for a full evaluation.

(37)

Species	:	Mouse
Sex	:	Male
Strain	:	C3H
Route of admin.	:	Dermal
Exposure period	:	80 weeks
Frequency of treatm.	:	Twice weekly
Doses	:	50 mg/application
Result	:	Negative
Control group	:	Untreated control and positive control (BaP)
GLP	:	No
Method	:	50 mg petrolatum was painted on the skin of 50 individually housed male mice, twice weekly for 80 weeks. The animals were shaved bi-weekly with electric clippers and the test material applied to the shaven intrascapular region. Treatment was continued for 80 weeks. A concurrent negative untreated control and a positive control (benzo-a-pyrene) was included in the study.

The study was repeated using 25 mg/application, twice weekly.

Remark : This report is a summary of results from an extensive program of studies. Consequently all the experimental details have not been presented. The authors state that such details are available in the original laboratory reports.

Result : No skin tumors developed in any of the mice to which petrolatum had been applied in either of the studies. The responses in the control groups is not reported.

Test substance : Petrolatum CAS No. 8009-03-8

Reliability : (3) Not assignable.
The report summarizes data from many studies and does not contain sufficient detail for a full evaluation.

(37)

Species : Mouse
Sex : Male/female
Strain : Swiss
Route of admin. : Dermal
Exposure period : Lifetime
Frequency of treatm. : Twice weekly
Doses : Approximately 60 microlitres per application
Result : Negative
Control group : Yes, concurrent vehicle
Year : 1966
GLP : No data
Test substance : 15% solution of Amber Petrolatum (NF Grade) in isooctane.
Method : Three drops (approximately 60 microlitres) of a 15% solution of amber petrolatum in isooctane was applied to the shaven skin of the mice, twice weekly for their lifetimes.
30 male and 40 female mice were treated in this way.
A group of 50 males and 50 females served as vehicle controls and received 60 microlitres of isooctane twice weekly for the lifespan of each animal. Animals were housed in groups of not more than 10 per cage.
The occurrence of skin tumors and other lesions in the treated area and other visible lesions was noted and their progression recorded.
Histological confirmation of each lesion was confirmed after autopsy of the respective animals.

Result : Treatment with petrolatum caused moderate epidermal hyperplasia.
The authors state that the incidence of internal tumors appeared within the limits observed in the control animals.
Treatment did not appear to affect survival when compared to controls as follows:

	Survival(%) at weeks		
Group	**30**	**50**	**70**
Petrolatum			
Females	90	77	53
Males	93	83	35
Controls			
Females	90	80	64
Males	90	54	32

The skin tumor incidence is summarised below for the control and petrolatum groups. No data are included here for the various extracts of petrolatum that were tested, even though such data were given in the publication reviewed.

	Animals with tumors	Total number of Tumors	Carcinomas	Regressions	Latency (weeks)
Petrolatum					
Females	1	2*	-	1	100
Males	2	3**	-	2	69
Solvent					
Females	-	-	-	-	-
Males	2	2	1	-	63

* one papilloma on eyelid
** one papilloma under chin

Test substance : 15% solution of Amber Petrolatum (NF Grade) in isooctane.
Reliability : (2) Valid with restrictions.
The study was designed only to investigate skin carcinogenicity and consequently detailed pathological findings are not available. Detailed findings (histopathological) are not included in the paper, but the authors make reference to a source of such data.

(39)

Species : Mouse
Sex : Male/female
Strain : Swiss
Route of admin. : Dermal
Exposure period : Lifetime
Frequency of treatm. : 3 times weekly
Doses : 3 drops
Result : Negative
Control group : Yes, concurrent no treatment
Year : 1962
GLP : No data
Test substance : 5 waxes were selected from 36 samples on the basis of their ultraviolet absorptivity, representing the range of aromatic contents Each of the 5 waxes was dissolved in warm benzene to achieve 15% solutions. These were warmed in a water bath prior to application to the skin.
Additionally a benzene solvent control was included in the study as well as an aromatic extract (in is-octane) of one of the waxes and a 15% solution in benzene of a chromatographed wax.
Method : 3 drops (approximately equivalent to 0.05 ml) of the solution of wax or the solvent control was applied to the skin of the intrascapular region over an area of approx. 2 X 2 cm. This treatment was continued 3 times weekly to groups of mice throughout the experiment. Observation was continued until spontaneous death or until the animals were killed

when dying. All mice were subjected to a complete autopsy followed by an histological examination of all abnormal tissue.
Group sizes were approximately 60 male and 30 female for each wax sample and 140 mice of each sex for controls.

Result : Survival rates of the mice were similar for treated and control animals with a better survival among females than males.
Some desquamation and epilation occurred in the treated areas of skin after the first few applications and this persisted throughout the study.
Histologically, moderate epidermal hyperplasia was observed in both treated and control animals. The wax treated animals also had some focal areas of hyperplasia of the sebaceous glands. No degenerative or necrotic changes were observed.

The skin tumor incidences are shown in the following table.

Sample	No. of mice	Benign papillomas	Malignant carcinomas	Sebaceous gland adenomas	Other
Wax 2	61 M	1			
	30 F				
Wax 8	61 M	3	1		
	31 F	1			
Wax 12	58 M	4		1	1
	34 F	1		1	
Wax 15	57 M	2			
	30 F	1			
Wax 20	61 M	1		2	
	36 F	1		2	
Benzene	59 M		1		
	35 F	1			

A number of other tumors were also observed at autopsy (mainly lung adenomas, mammary carcinomas and malignant lymphomas) but these were found in all groups and their incidence was similar in wax treated groups and controls.
The authors judged that these studies were negative.

Reliability : (2) valid with restrictions
Although not conducted to GLP, the study was nevertheless, robust and is acceptable for the purpose of assessing the skin carcinogenicity potential of paraffin wax solutions in benzene.

(49)

Species	:	Mouse
Sex	:	Male
Strain	:	White albino
Route of admin.	:	Dermal
Frequency of treatm.	:	Three times weekly for lifetime
Year	:	1951
GLP	:	No
Test substance	:	Eight slack waxes and eight aromatic hydrocarbon extracts derived from the slack waxes were tested. [Because of the lack of detail in the publication it is not possible to establish whic aromatic extract from which specific slack wax]. The extracts were obtained by eluting, with an unspecified solvent, silica gel columns charged with the individual slack waxes. No additional information was provided on the preparation of the aromatic test materials. [However, in parallel studies on aromatic extracts collected from catalytically cracked oils, the investigators reported that the silica gel columns were eluted first with n-heptane to collect non-aromatic components of the oils and then with acetone to recover the aromatic components. In the parallel studies the recovered aromatics were tested on mice after evaporation of the acetone.]
Method	:	Approximately 15 mg of warmed test material were applied as a thin film by means of a small brush on Monday, Wednesday and Friday to the shorn scapular region of groups of 30 albino male mice. Test material application was continued until death. After tumors had appeared the test materials were applied around the viable base of the growths, not on their often "dead tops".

For each material at autopsy, sections were taken of representative tumors and any internal lesions of interest. These tissue sections were then examined microscopically. For each test material a cancer and a tumor index was calculated as follows:

Tumor index =

$$100 \times \frac{\text{Total No of animals in which tumors developed}}{\text{Original No. animals less No dead at 90 days without tumors}}$$

Cancer Index =

$$100 \times \frac{\text{Total No animals in which cancer developed}}{\text{Original No less No. dead at 90 days from causes other than cancer}}$$

Potency was calculated:= $\frac{\text{Cancer index}}{\text{Tumor index}}$

Result : Results are summarized in the following two tables:

Slack waxes

Wax Sample	**Oil (%)***	**CI/TI at Days 250**	**450**
145	25	4/23	8/10***
147	17	0/3	7/7

150	20	0/0	4/4
141	10	0/3	0/7
142	21	0/4	0/4
144	21	0/4	0/4
140	20	4/7	4/4***
146	12	0/0	4/4

Aromatic extracts

Sample	**Aromatic (%)****	**CI/TI at Days 250**	**450**
231	18	14/38	24/38****
233	0	19/30	23/35****
235	12	17/35	17/43****
228	7	3/17	14/34
229	0	0/0	0/13
230	12	0/42	8/30***/*****
231	11	4/22	4/30
232	8	0/8	4/10

* Oil content of the slack waxes (w/w)
** Aromatics content of the slack wax (w/w)
*** The lower tumor index (TI) at the later date is due to the spontaneous disappearance of some papillomas
**** The experiment was discontinued after 335 days
***** The experiment was discontinued after 490 days

The authors concluded that the slack waxes showed only a low order of carcinogenicity at 250 days. However by 450 days every sample of slack wax had elicited papillomas and for 5 of them cancers as well.
The aromatic extracts on the other hand exhibited a greater potency. At 250 days all but one sample had produced papillomas and 5 samples had produced cancers. At 450 days all but one sample had elicited cancers and all had elicited papillomas.

The authors concluded that the carcinogenicity of slack wax
1. Can be attributed to the aromatic compounds found in the oils from which the waxes were pressed and which are retained on the waxes as impurities.
2. Is not due to paraffins.

Another study from the same laboratory (Dietz et al, 1952) on 11 slack waxes (it is unclear whether some were the same samples as in Smith et al, 1951) produced similar results. The tumor potency of each sample was low to marginal.

Reliability : (3) Not assignable.
The study summarized here was conducted to identify the carcinogenic component(s) of slack waxes.
Although not conducted to GLP and lacking experimental deatils the study is important since it identifies the residual oil in the slack wax and not the paraffins as being responsible for carcinogenic activity

(18) (50)

Species	:	Rabbit
Sex	:	Male/female
Strain	:	New Zealand white
Route of admin.	:	Dermal
Frequency of treatm.	:	Three times weekly
Control group	:	Yes, concurrent vehicle
Year	:	1962
GLP	:	No
Test substance	:	5 waxes were selected from 36 samples on the basis of their ultraviolet absorptivity, representing the range of aromatic contents Each of the 5 waxes was dissolved in warm benzene to achieve 15% solutions. These were warmed in a water bath prior to application to the skin. Additionally a benzene solvent control was included in the study.
Method	:	Solutions of the waxes as well as the benzene alone were applied three times weekly to the shorn skin of the intrascapular region (approximately 10 X 10 cm) of 4 male and 4 female rabbits. Each application consisted of approximately 0.08 ml. The authors state that a few rabbits were added in some groups to compensate for death of other rabbits before one year of treatment. Specific details are not provided.
Remark	:	This study had not been completed at the time of publication of a paper on the toxicity of petroleum waxes (Shubik et al). However, the information is useful in assessing the skin carcinogenicity of petroleum waxes since it provides data from an additional species.
Result	:	Some reddening, desquamation and epilation of the painted skin area occured after a few paintings with the wax solutions and the benzene alone; these changes persisited throughout the study without any notable modifications. 2 small skin papillomas were observed in the male group painted with one of the waxes. One of these papillomas developed after 48 weeks of treatment and was still present at the 105th week. The other papilloma developed after 93 weeks and regressed at the 110th week. No other skin lesions were found in any of the groups.
Reliability	:	(4) Not assignable. This study was not reported thoroughly, nor was it complete at the time of publication. However it does provide supportive information from a species other than the mouse.

(49)

Species : Rat
Sex : Male/female
Strain : FDRL
Route of admin. : Oral feed
Exposure period : 2 years
Frequency of treatm. : Ad libitum
Doses : 5% in the diet
Result : Negative
Control group : Yes, concurrent no treatment
Year : 1965
GLP : No data
Test substance : Three blends of petrolatum were examined. They were as follows:

Blend A, a snow-white grade meeting USP XVI specifications. This sample was a blend in equal proportions of six commercially available materials, each meeting the US specification.

Blend B, a white petrolatum, somewhat darker than Blend A, but nevertheless meeting the USP XVI specification. This blend was also prepared as a mixture of six commercially available materials in equal proportions.

Blend C, a yellow petrolatum meeting NF XI specification. This blend was prepared as a mixture in equal proportions of 5 commercially available products.

The three blends were kept with minimum air space refrigerated in metal containers for the duration of the study.

Analytical characteristics of the blends were as follows:

Blend	UV absorptivity (290 micron)	Lovibond color (2 in. cell)	Specific gravity (60 °C)	Melting point (°C)
A	0.136	2Y	0.830	53.5
B	0.424	12Y 0.5R	0.835	52.2
C	1.48	35Y 10R	0.844	51.3

Method : 50 rats of each sex, individually housed were fed diets containing 5% of one of three blends of petrolatum ad-libitum for two years. A group of 100 rats of each sex served as controls and were fed normal diet ad-libitum that had been supplemented with 1% vitamin mix and 0.2% Aurofac 10.

The animals were observed daily for appearance, behavior and survival.

Weekly measurements were made of body weight for the first 12 weeks of the study and biweekly thereafter. Weekly measurements were also made of food intake for the first 12

weeks for 10 rats of each sex fed the diets containing petrolatum and for 20 rats of each sex fed control diet.

At 12, 26, 52, 72 & 100 weeks the following determinations were made on representative animals from each of the groups: red cell count and/or hematocrit, total and differential white cell counts, hemoglobin content, blood glucose and blood urea nitrogen levels.

Rats that died and survivors at the end of the study were autopsied and the following organ weights were recorded: liver, kidneys, spleen, heart, adrenals, thyroids and pituitary.

For all rats that died, that were killed in a moribund state or from representative surviving animals at the end of the 2 year feeding period (10 of each sex in the petrolatum groups, 20 of each sex controls) the following organs were fixed and examined histologically: liver, spleen, stomach, large and small intestine, pancreas, kidney, urinary bladder, adrenal, thyroid gland, testis or ovary, salivary gland, lymph node, heart, lung, muscle, skin, spinal cord, brain, thymus, bone marrow and "growths of any description".

Result : Growth rates were unaffected by exposure to petrolatum when compared to controls.
Although there were small statistically significant differences in food utilization values between control and some petrolatum exposed animals these were not of biological significance.
Survival at two years was unaffected when compared to controls. Survival of males was approximately 68% and that for females was 58%.
Neither hematological nor clinical chemical measurements were affected by exposure to any of the petrolatum samples either during or at the end of the study.
No differences were found at autopsy between petrolatum exposed and control animals. Furthermore there were no histological changes that could be attributed to dietary exposure to petrolatum. Histological changes that occured did so in both sexes and in all treatment and control groups and were considered to be ageing related.
Neither of the 3 petrolatum blends caused an increased tumor incidence in any tissue/organ examined.

Reliability : (2) Valid with restrictions.
This study is well conducted and reported, but was carried out prior to the need for GLP. Nevertheless the study is valid

(46)

Species	:	Rat
Sex	:	Male/female
Strain	:	Sprague-Dawley
Route of admin.	:	Oral feed
Exposure period	:	2 years
Frequency of treatm.	:	Continuous
Doses	:	5000mg/kg bw/day
Result	:	Negative
Control group	:	Yes, concurrent no treatment
Year	:	1962
GLP	:	No
Test substance	:	5 waxes were selected from 36 samples on the basis of their ultraviolet absorptivity, representing the range of aromatic contents Each of the 5 waxes was ground into a powder and added to powdered diet and mixed in the proportion 1:9 w/w.
Method	:	Each of the five waxes were fed ad-libitum to male and female rats at a dietary concentration of 10% for 2 years. An additional group of 140 male and 157 females were fed control diet. The rats inspected and weighed every second week and all gross lesions were recorded. This was continued until the rats died or were killed when dying and were then submitted to complete autopsy followed by histological examination of all abnormal tissue.
Result	:	Survival rates and growth rates were unaffected by oral exposure to any of the waxes tested. A number of tumors were found in all groups at autopsy. The incidence of each tumor type was reported. The number of tumor bearing animals was similar to that of controls and furthermore the incidence of the various tumor types was also similar in treated and control animals. No other toxic effects were found at histological examination. The authors concluded that the five waxes were devoid of carcinogenic or other toxic action when fed at a level of 10% in the diet.
Reliability	:	(2) Valid with restrictions. Study not carried out acording to GLP and only "abnormal" tissue examined histologically. Study provided supportive information only and coul not be used as a definitive study.

(49)

Species	:	Rat
Strain	:	BD I, BD III and W
Route of admin.	:	Various
Exposure period	:	Up to approximately 2.5 years
Frequency of treatm.	:	Various
Year	:	1953
GLP	:	No
Test substance	:	Various including yellow vaseline

Remark : The following is taken from the method section of an English translation of the German report:

> "Liquid paraffin (DAB. 6) was injected into 30 rats, 2.5 ml once subcutaneously and intraperitoneally in a total dose of 9 ml per animal divided over 15 individual injections over a period of 40 weeks. Another 30 rats obtained the liquid paraffin in the food. The total dose was 136 ml/animal in 500 days.
>
> Yellow vaseline (DAB. 6) was also injected after warming. Eight rats obtained 3 ml intraperitoneally and 26 rats 1 ml subcutaneously besides. All animals were observed until spontaneous death....."

The following is taken from the results section of the publication.

> "In the experiment with vaseline a tumor developed at the injection point after a latent period of 658 days. Histologically this tumor turned out to be an osteo-sarcoma. ....."

Reliability : (4) Invalid.
This study is of historical interest only and is included for completeness only.

(48)

Species : Mouse
Sex : Male/female
Strain : Swiss Webster
Route of admin. : s.c.
Frequency of treatm. : Single subcutaneous dose
Post exposure period : 18 months
Doses : 100 mg
Result : Negative
Control group : Yes
Year : 1965
GLP : No
Test substance : Three blends of petrolatum were examined. They were as follows:

Blend A, a snow-white grade meeting USP XVI specifications. This sample was a blend in equal proportions of six commercially available materials, each meeting the US specification.

Blend B, a white petrolatum, somewhat darker than Blend A, but nevertheless meeting the USP XVI specification. This blend was also prepared as a mixture of six commercially available materials in equal proportions.

Blend C, a yellow petrolatum meeting NF XI specification. This blend was prepared as a mixture in equal proportions of 5 commercially available products.

The three blends were kept with minimum air space refrigerated in metal containers for the duration of the study.

Analytical characteristics of the blends were as follows:

Blend	UV absorptivity (290 micron)	Lovibond color (2 in. cell)	Specific gravity (60 °C)	Melting point (°C)
A	0.136	2Y	0.830	53.5
B	0.424	12Y 0.5R	0.835	52.2
C	1.48	35Y 10R	0.844	51.3

Stripped lard was used as negative control substance.

Method : A single dose of 100 mg of one of the three petrolatum blends or stripped lard was administered subcutaneously into the intrascapular region of 28 day old mice. 50 male and 50 female mice were used for each group and these were housed individually for the following 18 month observation period.
The mice were allowed food and water ad-libitum.
Growth, physical appearance and behavior were observed throughout the study and special attention was paid to the injection site.
Representative mice sacrificed at 9 months and all mice that died or were sacrificed at the end of the 18 month observation period were examined at autopsy for evidence of

pathological change. Weights of liver, spleen and kidneys were recorded. After fixation, histological examination was made of: liver, spleen, stomach, small and large intestine, pancreas, kidney, urinary bladder, adrenal, thyroid, testis or ovary, salivary gland, lymph node, heart, muscle, lung, skin, spinal cord, brain, thymus and bone marrow and any macroscopically observed growths.

Result : Growth rates, food intakes and food utilization was unaffected by s.c. administration of any of the petrolatum samples when compared to the control group. The males consumed slightly more food than the females, but there were no differences between the various treatment groups.
Mortality was similar in the control and petrolatum groups and overall survival ranged between 12 and 24% at the end of the study (78 weeks).
Liver, kidney and spleen weights were not affected by exposure to any of the petrolatum blends.
Gross observations at autopsy were spread equally amongst all groups and were not specifically related to exposure to petrolatum.
At about 7-9 months, there had been a significant rise in mortality in all groups and histopathlogical examination confirmed widespread leukemic infiltration with secondary septicemic involvement in some animals in all groups.
Gross findings at the end of the study were consistent with ageing animals. The responses were largely either of a chronic inflammatory or fibrotic nature. Many of the observations in the lymphatic system showed chronic changes associated with the clearance of the foreign material that had been injected subcutaneously.
There was no specific relationship between tumor incidence and the test material injected.

In conclusion, no toxic or carcinogenic response resulted as a consequence of the s.c. injection of a 100 mg dose of either of the 3 petrolatum blends.

Reliability : (2) Valid with restrictions.
This study is well conducted and reported, but was carried out prior to the need for GLP. Although survival of mice was poor, nevertheless the study is considered valid.

(46)

Species	:	Mouse
Sex	:	Male/female
Strain	:	Swiss
Route of admin.	:	s.c.
Exposure period	:	Lifetime
Frequency of treatm.	:	Once only administration of test material
Post exposure period	:	Lifetime
Year	:	1962
GLP	:	No
Test substance	:	paraffin wax
Method	:	A single wax disc (2 cm. diameter, 2 mm. thick and weighing 0.5 g) was implanted subcutaneously in groups of approximately 45 male and 50 female Swiss mice. This was done for 5 different waxes. Additionally, 0.5 g of one of the waxes was implanted as a powder in a further group of 48 and 46 female Swiss mice. The animals and their controls were observed for their lifetimes.
Result	:	Tumors developed at the implantation sites of the wax discs. No tumors developed at the site s of the powdered wax. This finding is consistent with other reports on the tumorigenicity of implanted inert materials. It is generally believed that tumorigenicity at subcutaneous implantation sites is a function of the physical form of the material rather than of the material itself. If however, the material had been tumorigenic it would be expected that tumors would have developed at the site of the implanted powder.
Reliability	:	(2) Valid with restrictions. Although the study was not GLP compliant it nevertheless was properly conducted and reported.

(49)

5.10 EXPOSURE EXPERIENCE

: **Slack wax**
There are no published reports of acute effects in humans with slack waxes, but they are expected to be essentially non-toxic because both the residual oil and the wax components themselves are not acutely toxic.

There have been several reports of human occupational cancer amongst wax pressmen, during the preparation of paraffin wax (Hendricks et al, 1959; Lione and Denholm, 1959). In the process of wax pressing the unrefined or poorly refined oil was chilled and the solidified crude wax (slack wax) removed from the viscous oil on filter presses. This crude wax may have contained as much as 20-40% unrefined/poorly refined oil, which was reduced to less than 0.5% in subsequent processing. It should be noted that wax pressing is no longer used as a process and has been replaced by more

modern techniques.

(32) (40)

: **Paraffin wax and Microcrystalline wax**
A review of the clinical studies with two undiluted paraffin waxes and formulated products containing various concentrations of paraffinic (5-16%) and microcrystalline (4.35-15%) waxes was published (Anon, 1984). These studies include a range of acute and repeat application tests in groups of humans for skin irritation and skin sensitization. All products gave, at most, slight erythema and none caused skin sensitization.

The widespread use in cosmetic and in cosmetic surgery over many years demonstrates the low toxicity of refined waxes and many guidelines exist for their safe use (Hjorth, 1987). Notwithstanding this, there are occasional reports of adverse effects with these products. Subcutaneous deposits often referred to as paraffinoma, have been described frequently following injection of these materials under the skin but these are not normally associated with other progressive changes.

There has been one report where an outbreak of skin rashes was attributed to occupational exposure to wax fume (Halton & Piersol, 1994).

(21) (28) (33)

: **Petrolatum**
Despite the widespread use of petrolatum for many years as a vehicle in human skin patch testing, isolated cases of allergy to petrolatum have been reported. Neverthelesss, petrolatum is still considered to be a good vehicle for patch testing. Fisher has concluded that although allergic reactions to petrolatum are rare, white, and not yellow petrolatum should be used as a vehicle in human skin patch testing.

(17) (20) (26) (27)

(1) Abernathy, S., D. Mackay, L. McCarty (1988).
Volume fraction correlation for narcosis in aquatic organisms: the key role of partitioning,
Environ Toxicol Chem 7, 469-481

(2) ACGIH (1998) Threshold limit values (TLVs) for chemical substances and physical agents and biological exposure indices (BEIs)
Cincinnati OH, American Conference of Governmental Industrial Hygienists

(3) Adema, D.M.M. (1991)
The acute aquatic toxicity of alkylbenzenes. Dutch contribution to collecting data with respect to Annex II of Marpol 1973/1978.
Progress report no. 1 for 1990 and 1991.
Report No. R 91/198. Delft: TNO

(4) Adema, D.M.M. and van den Bos Bakker, G.H. (1986)
Aquatic toxicity of compounds that may be carried by ships (Marpol 1973, Annex II). Progress report for 1986 from TNO to the Dutch Ministry of Housing, Physical Planning and Environment.
Report No. R 86/326a. Delft: TNO.

(5) American Petroleum Institute

(6) Battersby, N. F, Pack, S. E and Watkinson, R. J. (1992)
A correlation between the biodegradability of oil products in the CEC L-33-T-82 and Modified Sturm tests
Chemosphere Vol 24, No 12, pp 1989-2000

(7) Bennet, H. (1975)
Industrial waxes. Volume 1: Natural & synthetic waxes.
New York: Chemical Publishing Company Inc.

(8) BIBRA (1992)
A 90-day feeding study in the rat with six different mineral oils [N15 (H), N70 (H), N70 (A), P15 (H), N 10(A) and P100 (H)], three different mineral waxes (a low melting point wax, a high melting point wax and a high suphur wax) and coconut oil.
BIBRA Project No: 3.1010

(9) BIBRA (1993)
A 90-day feeding study in the rat with two mineral waxes identified as paraffin wax 64 (OFH-064) and micro/parrafin wax mixture.
BIBRA Project No. 3.1205

(10) BIBRA (1999)
A subchronic 90-day dietary toxicity study of a low melting point paraffin wax in two rat strains
Study No. 95-2394, API study No. HES1516-L-00880-Oral

(11) CEFIC (2000)
The classification of petroleum solvent streams and related complex hydrocarbon solvents for aquatic environmental effects under the EU dangerous substances directive.
Brussels: Hydrocarbon Solvents Producers Association

(12) CONCAWE (1984)
Assessment and comparison of the composition of food-grade white oils and waxes manufactured from petroleum by catalytic hydrogenation versus conventional treatment.
Report No. 84/60
CONCAWE, Den Haag. August 1984

(13) CONCAWE (1993)
White oil and waxes - summary of 90-day studies
Report No. 93/56

(14) CONCAWE (1997)
Lubricating oil basestocks
Product dossier No. 97/108
CONCAWE, Brussels

(15) CONCAWE (1999)
Petroleum waxes and related products
Product dossier No. 99/110

(16) CONCAWE (2001)
Environmental classification of petroleum substances - Summary data and rationale.
Report 01/54
CONCAWE, Brussels

(17) Conti, A., Manzini, B. M., Schiavi, M. E. and Motolese, A. (1995)
Sensitization to white petrolatum used as a vehicle for patch testing.
Contact Dermatitis Volume 33, pages 201-202.

(18) Dietz, W. A., King Jr., W. H., Priestley Jr. W. and Rehner, J. (1952)
Properties of high boiling petroleum products
Ind. Eng. Chem. Vol. 44., No 8., pp. 1818-1827

(19) Donkin, P., J. Widdows, S.V. Evans, M.D. Brinsley (1991).
QSARs for the sublethal response of marine mussels (Mytilus edulus) Sci Tot Environ 109/110, 461-474

(20) Dooms-Goosens, A. and Degreef, H. (1983)
Contact allergy to petrolatums (1) Sensitizing capacity of different brands of yellow and white petrolatums.
Contact Dermatitis Volume 9, Pages 175-185.

(21) Elder, R (1984)
Final Report on the Safety Assessment of Fossil and Synthetic Waxes
Editor R. Elder
J. Am. College of Toxicology Volume 3, number 4, pages 43-99

(22) EU (1996)
Technical guidance document in support of Commission Directive 93/67/EEC on risk assessment for new notified substances and Commission Regulation (EC) 1488/94 on risk assessment for existing substances. Part IV, Chapter 4: Use of quantitative structure activity relationships (QSARs) in risk assessment. Luxembourg Office for Official Publications of the European Communities

(23) EWF (1990)
Specifications for petroleum derived hydrocarbon waxes - food grade
Brussels: European Wax Federation

(24) Exxon Biomedical Sciences Inc.
C. Lee Personal Communication to S. Fraser, Environment Canada 01EMBSI.748;2001EMBSI.ZZJNK; and 01EMBSI.749;2001EMBSI.ZZJNK

(25) Exxon Biomedical Sciences, Inc. (1995).
Ready Biodegradability, Manometric Respirometry.
Study #102094A.

(26) Fisher, A. A. (1981)
Cutaneous reactions to petrolatum
Cutis, Volume 28 Pages 23--, 24, 31, 57 & 93.

(27) Frankel, E. B. (1985)
Letter to the editor: Acne secondary to white petrolatum use
Arch. Dermatol. Vol. 121, pages 589-590.

(28) Halton, D. M. and Piersol, P. (1994)
Investigations into an outbreak of rashes in a wax coating treatment process.
Appl. Occup. Environ. Hyg. Vol 9, No 12, pp 941-944

(29) Hanstveit, (1991).
A study of the fate of waxed paper materials in a woodland litter layer.
TNO Report No. R 90/243a

(30) Hanstveit, A. O. (1990)
Inherent Biodegradability of Waxes. TNO-Report No R 90/198b

(31) Harris, J.C. 1982.
Rate of Hydrolysis. In Handbook of Chemical Property Estimation Methods. p. 7-6.
W. J. Lyman, W.F. Reehl and D.H. Rosenblatt, eds.
McGraw-Hill Book Company, New York, NY, USA.

(32) Hendricks, N. V. et al (1959)
Cancer of the scrotum in wax pressmen
I. Epidemiology. AMA Arch. Ind. Health Vol 19, pp 524-529

(33) Hjorth, N. (1987)
Diagnostic patch testing.
In: Marzuli, F. N. and Maibach, H. I. (Eds)
Dermato-toxicology (3rd edition). Chapter 13, pp 307-317
Washington DC: Hemisphere Publishing Corp.

(34) IBR (1976)
Akute Toxizitotsprufung von "R 9107" nach oraler applikation an der ratte
International Bio-Research Inc. Report No. 1-4-195/1-76

(35) IBR (1976)
Akute Toxizitotsprufung von "R 9269" nach oraler Applikation an der ratte.
International Bio-Research Inc. Report No. 1-4-195/2-76.

(36) JECFA (1996)
Toxicological evaluation of certain food additives and contaminants. Prepared by the 44th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
WHO Food Additives Series 35. Geneva.

(37) Kane, M. L., Ladov, E. W., Holdsworth, C. E. and Weaver, N. K. (1984)
Toxicological characteristics of refinery streams used to manufacture lubricating oils.
American Journal of Industrial Medicine Vol 5. 183-200

(38) Kaufman, J. J. and Weisberger, G. A. (1993)
Petroleum waxes, including petrolatums.
ASTM Manual on significance of tests for petroleum products (6th ed). Chapter 10.

(39) Lijinsky, W., Saffiotti, U. & Shubik, P. (1966)
Skin Tumorigenesis by an Extract of Amber Petrolatum.
Toxicology and Applied Pharmacology Vol. 8, 113-117

(40) Lione, J. G. and Denholm, J. S. (1959)
Cancer of the scrotum in wax pressmen
II. Clinical observations. AMA Arch. Ind. Health Vol 19, pp 530-539

(41) Mackay, D, A. DiGuardo, S. Paterson, & C. Cowan, EQC Model, ver. 1.01, 1997, available from the Environmental Modelling Centre, Trent University, Canada.

(42) McCarty, L.S. et al (1991)
Interpreting aquatic toxicity QSARs: the significance of toxic body residues at the pharmacologic endpoint.
In: Hermens, J.L.M. and Opperhuizen, A. (Eds).
QSAR in environmental toxicology. Volume IV, p. 515-525.
Amsterdam: Elsevier.

(43) Meylan, M, SRC 1994-1999.
AOPWIN is contained in the computer program EPIWIN (Estimate ver. 3.04), available from Syracuse Research Corp.

(44) Meylan, M, SRC 1994-1999.
LOGKOWWIN is contained in the computer program EPIWIN (Estimate ver. 3.04), available from Syracuse Research Corp.

(45) Mobil Oil Corporation (1984-1991)
Unpublished data cited in
CONCAWE (1997)
Lubricating oil basestocks
Product dossier No. 97/108

(46) Oser, B. L., Oser, M., Carson, S. & Sternberg, S. S. (1965)
Toxicologic Studies of Petrolatum in Mice and Rats
Toxicology and Applied Pharmacology Vol 7, 382-401

(47) SCF (1995)
Opinion on mineral and synthetic hydrocarbons (expressed on 22 September 1995).
CS/ADD/MsAd/132-Final. Brussels, European Commission

(48) Schmahl, D. and Reiter A. (1953)
Experiments to create cancer with liquid paraffin, yellow petrolatum and wool fat.
Arxneimittel-Forschungen Vol 3, pp 403-406

(49) Shubik, P., Saffiotti, U., Lijinsky, W., Pietra, G., Rappaport, H., Toth, B., Raha, C. R., Tomatis, L., Feldman, R. and Ramaha, H. (1962)
Studies on the Toxicity of Petroleum Waxes.
Toxicol. Appl. Pharmacol. Volume 4, Supplement 1-62

(50) Smith, W. E., Sunderland, D. A. and Sugiura, K. (1951)
Experimental analysis of the carcinogenic activity of certain petroleum products.
Arch. Ind. Hyg. Occ. Med. Volume 4, pp 299-314

(51) UK HSE (1999) Occupational exposure limits 1999.
HSE Guidance Note EH40/99.
Health and Safety executive, London

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F003 8002-74-2
F012 N
F010 30-08-2000
F004 12031538
F005 21-07-2000
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F006 12031538
F007 21-07-2000
F008 Robust summary
F009 A35-01
EOB
C
B101 GI_GENERAL_INFORM_TAB
F001 28
F002 1
F003 30-08-2000
F004 IUC31
F010 A04-06
F011 A19-03
EOB
C
B102 GI_SYNONYM_TAB
F001 28
F002 1
F003 24-04-2001
F004 IUC31
EOB
C
B109 GI_EXPO_LIMIT_TAB
F001 28
F002 1
F003 30-10-2000
F004 IUC31
F007 A17-07
F008 2
F009 A16-03
EOB
C
B126 GI_ADD_REVIEWS_TAB
F001 28
F002 1
F003 22-07-2002
F004 IUC31
F007 EU SCF
EOR
F001 28
F002 3
F003 06-08-2002
F004 IUC31
F007 WHO JECFA
EOR
F001 28
F002 4
F003 22-07-2002
F004 IUC31
F007 CTFA
EOB
C
B201 PC_MELTING_TAB
F001 28
F002 2
F003 29-01-2003
F004 IUC4

```
F007 A02-03
F008 43
F009 63
F012 P01-03: ASTM D127
F013 1999
F014 A03-02
F020 A01-03: Slack wax
EOR
F001 28
F002 3
F003 29-01-2003
F004 IUC4
F007 A02-03
F008 43
F009 68
F012 P01-03: ASTM D127
F013 1999
F014 A03-02
F020 A01-03: Paraffin wax
EOR
F001 28
F002 4
F003 29-01-2003
F004 IUC4
F007 A02-03
F008 60
F009 95
F012 P01-03: ASTM D127
F013 1999
F014 A03-02
F020 A01-03: Microcrystalline wax
EOR
F001 28
F002 5
F003 29-01-2003
F004 IUC4
F007 A02-03
F008 36
F009 60
F012 P01-03: ASTM D127
F013 1999
F014 A03-02
F020 A01-03: Petrolatum
EOB
C
B202 PC_BOILING_TAB
F001 28
F002 2
F003 12-12-2001
F004 IUC31
F007 A02-06
F008 350
F009 500
EOB
C
B213 PC_GRANULOMETRY_TAB
F001 28
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F002 1
F003 30-10-2000
F004 IUC31
EOB
C
B204 PC_VAPOUR_TAB
F001 28
F002 1
F003 24-02-2003
F004 IUC4
F007 A02-03
EOB
C
B205 PC_PARTITION_TAB
F001 28
F002 2
F003 12-02-2002
F004 IUC31
F014 A36-003
F007 A02-03
F008 4.7
F009 6.7
F011 P07-04: KOWWIN Version 1.65 (EPIWIN)
F012 2001
F016 A01-03: wax and related materials
EOB
C
B206 PC_WATER_SOL_TAB
F001 28
F002 1
F003 12-02-2002
F004 IUC31
F023 A36-003
F007 A02-03
F008 P08-02
F009 .027
F010 5.96
F011 25
F020 P09-03: WSKOW Version 1.36 (EPIWIN)
F021 2001
F025 A01-03: Wax and related materials
EOB
C
B208 PC_AUTO_FLAMM_TAB
F001 28
F002 1
F003 30-10-2000
F004 IUC31
EOB
C
B209 PC_FLAMM_TAB
F001 28
F002 1
F003 30-10-2000
F004 IUC31
F007 P16-06
EOB
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C
B210 PC_EXPL_TAB
F001 28
F002 1
F003 30-10-2000
F004 IUC31
F007 P22-06: Not relevant
EOB
C
B211 PC_OXID_TAB
F001 28
F002 1
F003 30-10-2000
F004 IUC31
F007 P20-03: Not relevant
EOB
C
B212 PC_OTHER_TAB
F001 28
F002 1
F003 12-02-2002
F004 IUC31
F009 The information given in this section represent the range of values that
*    are found for the various waxes and related products.
EOB
C
B301 EN_PHOTODEGRADATION_TAB
F001 28
F002 1
F003 27-12-2001
F004 IUC31
F045 A36-003
F007 A01-03: Wax and related materials
F008 F01-02: Atmospheric oxidation
F009 F02-05: AOPWin Version 1.89 (EPIWIN)
F010 2001
EOB
C
B302 EN_STABILITY_IN_WATER_TAB
F001 28
F002 1
F003 27-12-2001
F004 IUC31
F040 A36-002
EOB
C
B305 EN_TRANSPORT_TAB
F001 28
F002 1
F003 25-02-2003
F004 IUC4
F011 A36-003
F007 F20-04: Calculated according to Mackay Level  I
F008 F22-01: Soil, air, water, suspended sediment, and sediment
F010 2000
EOB
C
```

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B308 EN_BIODEGRADATION_TAB
F001 28
F002 1
F003 06-08-2002
F004 IUC31
F047 A36-003
F048 1
F007 A01-03: Paraffin wax CAS 8002-74-2
F008 F25-01
F009 F26-25: Modified OECD 301B (significant modification, actually shake
*    flask test)
F010 1989
F011 F27-0166: Oil-contaminated soil from land-farming project
F020 F30-02: 80% in 28 days; inherently and extensively biodegradable
F046 A03-03
F052 84
F053 F05-01
F055 E34-02
EOR
F001 28
F002 2
F003 27-12-2001
F004 IUC31
F047 A36-003
F048 2
F007 A01-03: Microcrystalline wax CAS 63231-60-7
F008 F25-01
F009 F26-25: Modified OECD 301B (significant modification)
F010 1989
F011 F27-0166: Oil-contaminated soil from land-farming project
F020 F30-01
F046 A03-03
F052 84
F053 F05-01
EOR
F001 28
F002 3
F003 12-02-2002
F004 IUC31
F047 A36-003
F048 3
F007 A01-03: CAS 8002-74-2 and CAS 63231-60-7
F008 F25-01
F010 1989
F011 F27-0166: Naturally-occurring leaf-litter and soil biota (microbes and
*    invertebrates)
F052 6
F053 F05-04
EOR
F001 28
F002 4
F003 12-02-2002
F004 IUC31
F047 A36-003
F048 4
F007 A01-03: Paraffin wax CAS 8002-74-2
F008 F25-01
```

F009 F26-25: Shake flask test
F010 1989
F011 F27-0166: Unacclimated domestic sewage sludge supernatant and forest soil
F046 A03-02
F052 137
F053 F05-01
F055 E34-02
EOR
F001 28
F002 5
F003 27-12-2001
F004 IUC31
F047 A36-003
F048 5
F007 A01-03: Microcrystalline wax CAS 63231-60-7
F008 F25-01
F009 F26-25: shake flask test
F010 1989
F011 F27-0166: Unacclimated domestic sewage sludge supernatant and forest soil
F020 F30-02: Extensively biodegraded in long-term test
F046 A03-02
F052 137
F053 F05-01
F055 E34-02
EOR
F001 28
F002 6
F003 24-02-2003
F004 IUC4
F047 A36-002
F048 6
F007 A01-03: Slack wax (petroleum), hydrotreated CAS 92062-09-4
F009 F26-20
F010 1995
F011 F27-0139
F046 A03-03
F052 28
F053 F05-01
EOR
F001 28
F002 7
F003 24-02-2003
F004 IUC4
F048 7
F007 A01-03: Two white oils
F008 F25-01
F009 F26-16
F010 1984
F011 F27-0151
F012 20
F013 F28-02
F014 F29-03
F046 A03-02
EOB
C
B401 EC_FISHTOX_TAB
F001 28

F002 1
F003 27-03-2003
F004 IUC4
F033 A36-003
F007 A01-03: Various lubricating base oils
F008 E01-04
F009 E02-0101
F010 E03-03
F011 1990
F012 96
F013 E04-02
F014 E05-02
F031 A03-03
F032 A03-03
EOB
C
B402 EC_DAPHNIATOX_TAB
F001 28
F002 1
F003 25-03-2003
F004 IUC4
F032 A36-003
F007 A01-03: Various paraffin hydrocarbons, C5 to C14, normal, iso- and cyclo
*   structures
F008 E06-0034: Daphnia magna, Chaetogammarus marinus and Mysidopsis bahia
F009 E07-04: Not stated
F010 1986
F013 E05-02
F030 A03-03
F031 A03-01
F042 E01-03: Static and semi-static tests
EOR
F001 28
F002 2
F003 27-03-2003
F004 IUC4
F032 A36-003
F007 A01-03: Lubricating base oil CAS 64741-97-5, solvent refined light
*   naphthenic distillate
F008 E06-0034: Daphnia magna and Gammarus pulex
F009 E07-03
F013 E05-02
F030 A03-03
F031 A03-03
F042 E01-04
EOB
C
B403 EC_ALGAETOX_TAB
F001 28
F002 1
F003 27-03-2003
F004 IUC4
F036 A36-003
F007 A01-03: Various lubricating base oils
F008 E08-0055
F009 E09-03
F010 1990

```
F012 96
F013 E04-02
F014 E05-02
F034 A03-03
F035 A03-03
EOB
C
B406 EC_CHRONDAPHNIATOX_TAB
F001 28
F002 1
F003 27-03-2003
F004 IUC4
F030 A36-003
F007 A01-03: Various base oils
F008 E06-0010
F009 E16-01
F011 E17-02: Reproduction/survival
F012 21
F013 E18-01
F014 E05-02
F028 A03-03
F029 A03-03
EOB
C
B412 EC_OTHER_TAB
F001 28
F002 1
F003 25-03-2003
F004 IUC4
F009 Comments relating to physical size and number of carbon atoms in waxes
*    and related materials
EOR
F001 28
F002 2
F003 12-02-2002
F004 IUC31
F009 Comments relating to slack wax
EOR
F001 28
F002 3
F003 25-03-2003
F004 IUC4
F009 Comments relating to partition coefficient
EOB
C
B501 TO_ACUTE_ORAL_TAB
F001 28
F002 1
F003 22-02-2003
F004 IUC4
F017 A36-002
F018 1
F007 A01-03: Paraffin wax
F008 T01-03
F009 T02-24
F010 T03-03
F011 1976
```

F012 A02-04
F013 5000
F015 T04-01
F016 A03-02
F019 T24-03
F020 10
F021 T52-003: arachis oil
F022 T23-47
EOR
F001 28
F002 2
F003 22-02-2003
F004 IUC4
F017 A36-002
F018 2
F007 A01-03: Microcrystalline wax
F008 T01-03
F009 T02-24
F010 T03-03
F011 1976
F012 A02-04
F013 5000
F015 T04-01
F016 A03-02
F019 T24-03
F020 10
F021 T52-003: arachis oil
F022 T23-47
EOB
C
B502 TO_ACUTE_INHAL_TAB
F001 28
F002 1
F003 29-11-2001
F004 IUC31
EOB
C
B503 TO_ACUTE_DERMAL_TAB
F001 28
F002 1
F003 05-06-2002
F004 IUC31
F017 A36-005
F007 A01-03: Paraffin wax/Petrolatum (50/50)
F008 T01-03
F009 T02-23
F011 1972
F012 A02-04
F013 4000
F015 T04-01
F016 A03-01
F019 T24-04
F021 T52-005
F022 T23-47
EOB
C
B505 TO_SKIN_IRRITATION_TAB

F001 28
F002 1
F003 30-10-2000
F004 IUC31
F014 A36-005
F008 T02-23
F009 T14-06
F010 1984
F012 T46-06
F013 A03-02
F017 T49-001
F018 T50-001
F019 24
F020 T55-001
F021 9
EOB
C
B506 TO_EYE_IRRITATION_TAB
F001 28
F002 1
F003 30-10-2000
F004 IUC31
F014 A36-005
F008 T02-23
F009 T16-04
F010 1984
F012 T46-07
F013 A03-02
F016 50
F017 T49-002
F018 .1
F019 T56-001
F020 72
F021 T08-01
F022 6
F023 T51-002
EOB
C
B508 TO_REPEATED_DOSE_TAB
F001 28
F002 1
F003 21-03-2003
F004 IUC4
F030 A36-002
F031 1
F007 A01-03: One sample of paraffin wax & two samples of microcrystalline wax
F008 T02-24
F009 T23-16
F010 T24-03
F011 T25-09
F012 T26-10
F013 1992
F014 90 days
F015 Continuous in food
F017 0.002, 0.02, 0.2 & 2.0% in the diet
F018 T27-04
F029 A03-03

EOR
F001 28
F002 2
F003 28-01-2003
F004 IUC4
F008 T02-24
EOB
C
B509 TO_GENETIC_IN_VITRO_TAB
F001 28
F002 1
F003 29-11-2001
F004 IUC31
EOB
C
B510 TO_GENETIC_IN_VIVO_TAB
F001 28
F002 1
F003 29-11-2001
F004 IUC31
EOB
C
B511 TO_CARCINOGENICITY_TAB
F001 28
F002 1
F003 23-07-2002
F004 IUC31
F020 A36-005
F007 A01-03
F008 T02-18
F009 T23-07
F010 T24-02
F011 T38-01
F014 80 weeks
F015 Twice weekly
F017 50 mg/application
F018 T27-03: untreated control and positive control (BaP)
F019 A03-01
F022 T33-02
EOR
F001 28
F002 2
F003 06-08-2002
F004 IUC31
F020 A36-005
F007 A01-03
F008 T02-18
F009 T23-07
F010 T24-02
F011 T38-01
F014 80 weeks
F015 Twice weekly
F017 50 mg/application
F018 T27-03: untreated control and positive control (BaP)
F019 A03-01
F022 T33-02
EOR

F001 28
F002 3
F003 12-02-2002
F004 IUC31
F020 A36-003
F007 A01-03
F008 T02-18
F009 T23-45
F010 T24-03
F011 T38-13
F012 T39-05
F013 1965
F015 Single subcutaneous dose
F016 18 months
F017 100 mg
F018 T27-07
F019 A03-01
F022 T33-02
EOR
F001 28
F002 4
F003 12-02-2002
F004 IUC31
F020 A36-003
F007 A01-03
F008 T02-24
F009 T23-48: FDRL
F010 T24-03
F011 T38-10
F012 T39-05
F013 1965
F014 2 years
F015 Ad libitum
F017 5% in the diet
F018 T27-04
F019 A03-02
F022 T33-02
EOR
F001 28
F002 5
F003 05-06-2002
F004 IUC31
F020 A36-003
F007 A01-03: 15% solution of Amber Petrolatum (NF Grade) in isooctane.
F008 T02-18
F009 T23-44
F010 T24-03
F011 T38-01
F012 T39-05
F013 1966
F014 Lifetime
F015 Twice weekly
F017 Approximately 60 microlitres per application
F018 T27-05
F019 A03-02
F022 T33-02
EOR

F001 28
F002 6
F003 12-02-2002
F004 IUC31
F020 A36-003
F007 A01-03
F008 T02-18
F009 T23-44
F010 T24-03
F011 T38-01
F012 T39-05
F013 1962
F014 Lifetime
F015 3 times weekly
F017 3 drops
F018 T27-04
F019 A03-02
F022 T33-02
EOR
F001 28
F002 7
F003 21-08-2000
F004 IUCLID3
F020 A36-005
F008 T02-23
F009 T23-31
F010 T24-03
F011 T38-01
F012 T39-05
F013 1962
F015 three times weekly
F018 T27-05
F019 A03-01
EOR
F001 28
F002 8
F003 21-08-2000
F004 IUCLID3
F020 A36-003
F008 T02-24
F009 T23-42
F010 T24-03
F011 T38-10
F012 T39-05
F013 1962
F014 2 years
F015 Continuous
F017 5000mg/kg bw/day
F018 T27-04
F019 A03-01
F022 T33-02
EOR
F001 28
F002 9
F003 09-07-2002
F004 IUC31
F020 A36-005

F007 A01-03: Slack wax
F008 T02-18
F009 T23-48: white albino
F010 T24-02
F011 T38-01
F013 1951
F015 Three times weekly for lifetime
F019 A03-01
EOR
F001 28
F002 10
F003 10-06-2002
F004 IUC31
F020 A36-003
F007 A01-03: paraffin wax
F008 T02-18
F009 T23-44
F010 T24-03
F011 T38-13
F013 1962
F014 Lifetime
F015 Once only administration of test material
F016 Lifetime
F019 A03-01
EOR
F001 28
F002 12
F003 18-06-2002
F004 IUC31
F020 A36-004
F007 A01-03: various including yellow vaseline
F008 T02-24
F009 T23-48: BD I, BD III and W
F011 T38-12: various
F013 1953
F014 Up to approximately 2.5 years
F015 Various
F019 A03-01
EOB
C
B515 TO_HUMAN_EXPERIENCE_TAB
F001 28
F002 2
F003 25-06-2002
F004 IUC31
F010 3
EOR
F001 28
F002 3
F003 03-07-2002
F004 IUC31
F010 1
EOR
F001 28
F002 4
F003 25-06-2002
F004 IUC31

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F010 2
EOB
C
B601 TEXT_TAB
F002 28
F010 1.1.1
F004 1
F005 RM
F006 This robust summary covers the waxes and related products
**   which includes:
**   Slack wax
**   Petrolatum
**   Paraffin wax
**   Microcrystalline wax
**
**   Petroleum waxes are obtained from paraffinic refinery
**   streams  in lubricating oil manufacture.
**   The wax is sepa
F007 This robust summary covers the waxes and related products
**   which includes:
**   Slack wax
**   Petrolatum
**   Paraffin wax
**   Microcrystalline wax
**
**   Petroleum waxes are obtained from paraffinic refinery
**   streams  in lubricating oil manufacture.
**   The wax is separated by filtering a chilled solution of waxy
**   oil in a selected solvent (usually a mixture of methyl ethyl
**   ketone and toluene).
**
**   SLACK WAX is obtained from the dewaxing of refined or
**   unrefined vacuum distillate fractions. If the material has
**   been separated from residual oil fractions it is frequently
**   called PETROLATUM.
**   The slack waxes are  de-oiled by solvent crystallization or
**   "sweating" processes to manufacture commercial waxes with
**   low oil content. The oil that is separated from these
**   processes is known as FOOTS OIL.
**   The refined petroleum waxes are known as PARAFFIN WAXES.
**   MICROCRYSTALLINE WAXES have higher molecular weights than
**   the paraffin waxes and consist of substantial amounts of
**   iso- and cycloalkanes.
F020 1866
EOR
F002 28
F010 1.13
F004 1
F005 RE
F006 SCF (1995)
**   Opinion on mineral and synthetic hydrocarbons (expressed on
**   22 September 1995).
**   CS/ADD/MsAd/132-Final. Brussels, European Commission
F007 SCF (1995)
**   Opinion on mineral and synthetic hydrocarbons (expressed on
**   22 September 1995).
**   CS/ADD/MsAd/132-Final. Brussels, European Commission
```

F020 1867
EOR
F002 28
F010 1.13
F004 1
F005 RM
F006 The EU Scientific Committee for Food (SCF) reviewed the
** available information on mineral hydrocarbons, which
** included the petroleum waxes. Their opinion was published in
** 1995.
** The SCF reached the following conclusion:
**
** There are sufficient
F007 The EU Scientific Committee for Food (SCF) reviewed the
** available information on mineral hydrocarbons, which
** included the petroleum waxes. Their opinion was published in
** 1995.
** The SCF reached the following conclusion:
**
** There are sufficient data to allow a full Group ADI of 0-20
** mg/kg bw for waxes conforming to the following
** specification:-
**
** Highly refined waxes derived from petroleum based or
** synthetic hydrocarbon feedstocks, with
** viscosity not less than 11 mm2/s (cSt) at
100 deg C
** Carbon number not less than 25 at the 5%
boiling point
** Average molecular weight not less than 500
F020 1868
EOR
F002 28
F010 1.13
F004 3
F005 RE
F006 JECFA (1996)
** Toxicological evaluation of certain food additives and
** contaminants. Prepared by the 44th meeting of the Joint
** FAO/WHO Expert Committee on Food Additives (JECFA).
** WHO Food Additives Series 35. Geneva.
F007 JECFA (1996)
** Toxicological evaluation of certain food additives and
** contaminants. Prepared by the 44th meeting of the Joint
** FAO/WHO Expert Committee on Food Additives (JECFA).
** WHO Food Additives Series 35. Geneva.
F020 1869
EOR
F002 28
F010 1.13
F004 3
F005 RM
F006 The WHO Joint Expert Committee on Food Additives (JECFA)
** reviewed the available information on food grade mineral
** hydrocarbons. Their evaluation was published in 1996.
** With respect to waxes they made the following conclusions:
**

```
**   Substance
F007 The WHO Joint Expert Committee on Food Additives (JECFA)
**   reviewed the available information on food grade mineral
**   hydrocarbons. Their evaluation was published in  1996.
**   With respect to waxes they made the following conclusions:
**
**   Substance                      ADI
**                             (mk/kg bw)
**   Paraffin waxes
**   LMPW (Low melting point wax)         ADI withdrawn
**   IMPW ( Intermediate melting point wax)     ADI withdrawn
**
**   Microcrystalline waxes
**   HSW (High sulfur wax)                0-20
**   HMPW (High Melting Point Wax)        0-20
F020 1870
EOR
F002 28
F010 1.13
F004 4
F005 RE
F006 Elder, R (1984)
**   Final Report on the Safety Assessment of Fossil and
**   Synthetic Waxes
**   Editor R. Elder
**   J. Am. College of Toxicology Volume 3, number 4, pages 43-99
F007 Elder, R (1984)
**   Final Report on the Safety Assessment of Fossil and
**   Synthetic Waxes
**   Editor R. Elder
**   J. Am. College of Toxicology Volume 3, number 4, pages 43-99
F008 IUC31
F009 22-07-2002
F020 1871
EOR
F002 28
F010 1.13
F004 4
F005 RM
F006 An independent expert panel reviewed data supplied to them
**   by the Cosmetics, Toiletries & Fragrances Association
**   (CTFA). A report of the evaluation was published in 1984.
**   However, few experimental details are available and the
**   conclusions o
F007 An independent expert panel reviewed data supplied to them
**   by the Cosmetics, Toiletries & Fragrances Association
**   (CTFA). A report of the evaluation was published in 1984.
**   However, few experimental details are available and the
**   conclusions of the panel cannot be verified.
**   Their overall conclusion was:
**
**   Toxicological test data on Ozokerite, Ceresin, Montan Wax,
**   Paraffin, Microcrystalline Wax, Emulsifying Wax N.F., and
**   Synthetic Beeswax are presented. Based on the documented
**   animal and clinical test data, it is concluded that these
**   waxes are safe for use as cosmetic ingredients in the
**   present practices of concentration and use.
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F008 IUC31
F020 1872
EOR
F002 28
F010 1.2
F004 1
F005 RM
F006 Paraffin wax
** Slack wax
** Petrolatum
** Microcrystalline wax
F007 Paraffin wax
** Slack wax
** Petrolatum
** Microcrystalline wax
F008 IUC31
F020 1873
EOR
F002 28
F010 1.8.1
F004 1
F005 RE
F006 ACGIH (1998) Threshold limit values (TLVs) for chemical
** substances and physical agents and biological exposure
** indices (BEIs)
** Cincinnati OH, American Conference of Governmental
** Industrial Hygienists
F007 ACGIH (1998) Threshold limit values (TLVs) for chemical
** substances and physical agents and biological exposure
** indices (BEIs)
** Cincinnati OH, American Conference of Governmental
** Industrial Hygienists
F008 IUC31
F020 1874
EOR
F002 28
F010 1.8.1
F004 1
F005 RE
F006 UK HSE (1999) Occupational exposure limits 1999.
** HSE Guidance Note EH40/99.
** Health and Safety executive, London
F007 UK HSE (1999) Occupational exposure limits 1999.
** HSE Guidance Note EH40/99.
** Health and Safety executive, London
F008 IUC31
F020 1875
EOR
F002 28
F010 1.8.1
F004 1
F005 RM
F006 The UK HSE have established an occupational exposure limit
** of 2 mg/m3 (8 hour TWA) and a 15 minute Short Term Exposure
** Limit (STEL) of 6 mg/m3.
F007 The UK HSE have established an occupational exposure limit
** of 2 mg/m3 (8 hour TWA) and a 15 minute Short Term Exposure

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**   Limit (STEL) of 6 mg/m3.
F008 IUC31
F020 1876
EOR
F002 28
F010 2.1
F004 2
F005 RE
F006 Bennet, H. (1975)
**   Industrial waxes. Volume 1: Natural & synthetic waxes.
**   New York: Chemical Publishing Company Inc.
F007 Bennet, H. (1975)
**   Industrial waxes. Volume 1: Natural & synthetic waxes.
**   New York: Chemical Publishing Company Inc.
F008 IUC31
F020 1877
EOR
F002 28
F010 2.1
F004 2
F005 RE
F006 CONCAWE (1999)
**   Petroleum waxes and related products
**   Product dossier No. 99/110
F007 CONCAWE (1999)
**   Petroleum waxes and related products
**   Product dossier No. 99/110
F008 IUC31
F020 1878
EOR
F002 28
F010 2.1
F004 2
F005 RE
F006 EWF (1990)
**   Specifications for petroleum derived hydrocarbon waxes -
**   food grade
**   Brussels: European Wax Federation
F007 EWF (1990)
**   Specifications for petroleum derived hydrocarbon waxes -
**   food grade
**   Brussels: European Wax Federation
F008 IUC31
F020 1879
EOR
F002 28
F010 2.1
F004 2
F005 RE
F006 Kaufman, J. J. and Weisberger, G. A. (1993)
**   Petroleum waxes, including petrolatums.
**   ASTM Manual on significance of tests for petroleum products
**   (6th ed). Chapter 10.
F007 Kaufman, J. J. and Weisberger, G. A. (1993)
**   Petroleum waxes, including petrolatums.
**   ASTM Manual on significance of tests for petroleum products
**   (6th ed). Chapter 10.
```

F008 IUC31
F020 1880
EOR
F002 28
F010 2.1
F004 3
F005 RE
F006 Bennet, H. (1975)
** Industrial waxes. Volume 1: Natural & synthetic waxes.
** New York: Chemical Publishing Company Inc.
F007 Bennet, H. (1975)
** Industrial waxes. Volume 1: Natural & synthetic waxes.
** New York: Chemical Publishing Company Inc.
F008 IUC31
F020 1881
EOR
F002 28
F010 2.1
F004 3
F005 RE
F006 CONCAWE (1999)
** Petroleum waxes and related products
** Product dossier No. 99/110
F007 CONCAWE (1999)
** Petroleum waxes and related products
** Product dossier No. 99/110
F008 IUC31
F020 1882
EOR
F002 28
F010 2.1
F004 3
F005 RE
F006 EWF (1990)
** Specifications for petroleum derived hydrocarbon waxes -
** food grade
** Brussels: European Wax Federation
F007 EWF (1990)
** Specifications for petroleum derived hydrocarbon waxes -
** food grade
** Brussels: European Wax Federation
F008 IUC31
F020 1883
EOR
F002 28
F010 2.1
F004 3
F005 RE
F006 Kaufman, J. J. and Weisberger, G. A. (1993)
** Petroleum waxes, including petrolatums.
** ASTM Manual on significance of tests for petroleum products
** (6th ed). Chapter 10.
F007 Kaufman, J. J. and Weisberger, G. A. (1993)
** Petroleum waxes, including petrolatums.
** ASTM Manual on significance of tests for petroleum products
** (6th ed). Chapter 10.
F008 IUC31

F020 1884
EOR
F002 28
F010 2.1
F004 4
F005 RE
F006 Bennet, H. (1975)
** Industrial waxes. Volume 1: Natural & synthetic waxes.
** New York: Chemical Publishing Company Inc.
F007 Bennet, H. (1975)
** Industrial waxes. Volume 1: Natural & synthetic waxes.
** New York: Chemical Publishing Company Inc.
F008 IUC31
F020 1885
EOR
F002 28
F010 2.1
F004 4
F005 RE
F006 CONCAWE (1999)
** Petroleum waxes and related products
** Product dossier No. 99/110
F007 CONCAWE (1999)
** Petroleum waxes and related products
** Product dossier No. 99/110
F008 IUC31
F020 1886
EOR
F002 28
F010 2.1
F004 4
F005 RE
F006 EWF (1990)
** Specifications for petroleum derived hydrocarbon waxes -
** food grade
** Brussels: European Wax Federation
F007 EWF (1990)
** Specifications for petroleum derived hydrocarbon waxes -
** food grade
** Brussels: European Wax Federation
F008 IUC31
F020 1887
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F002 28
F010 2.1
F004 4
F005 RE
F006 Kaufman, J. J. and Weisberger, G. A. (1993)
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** Petroleum waxes, including petrolatums.
** ASTM Manual on significance of tests for petroleum products
** (6th ed). Chapter 10.
F008 IUC31
F020 1888

EOR
F002 28
F010 2.1
F004 5
F005 RE
F006 Bennet, H. (1975)
**   Industrial waxes. Volume 1: Natural & synthetic waxes.
**   New York: Chemical Publishing Company Inc.
F007 Bennet, H. (1975)
**   Industrial waxes. Volume 1: Natural & synthetic waxes.
**   New York: Chemical Publishing Company Inc.
F008 IUC31
F020 1889
EOR
F002 28
F010 2.1
F004 5
F005 RE
F006 CONCAWE (1999)
**   Petroleum waxes and related products
**   Product dossier No. 99/110
F007 CONCAWE (1999)
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**   Product dossier No. 99/110
F008 IUC31
F020 1890
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F002 28
F010 2.1
F004 5
F005 RE
F006 EWF (1990)
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**   food grade
**   Brussels: European Wax Federation
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**   food grade
**   Brussels: European Wax Federation
F008 IUC31
F020 1891
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F002 28
F010 2.1
F004 5
F005 RE
F006 Kaufman, J. J. and Weisberger, G. A. (1993)
**   Petroleum waxes, including petrolatums.
**   ASTM Manual on significance of tests for petroleum products
**   (6th ed). Chapter 10.
F007 Kaufman, J. J. and Weisberger, G. A. (1993)
**   Petroleum waxes, including petrolatums.
**   ASTM Manual on significance of tests for petroleum products
**   (6th ed). Chapter 10.
F008 IUC31
F020 1892
EOR

F002 28
F010 2.14
F004 1
F005 RE
F006 Bennet, H. (1975)
** Industrial waxes. Volume 1: Natural & synthetic waxes.
** New York: Chemical Publishing Company Inc.
F007 Bennet, H. (1975)
** Industrial waxes. Volume 1: Natural & synthetic waxes.
** New York: Chemical Publishing Company Inc.
F008 IUC31
F020 1893
EOR
F002 28
F010 2.14
F004 1
F005 RE
F006 CONCAWE (1999)
** Petroleum waxes and related products
** Product dossier No. 99/110
F007 CONCAWE (1999)
** Petroleum waxes and related products
** Product dossier No. 99/110
F008 IUC31
F020 1894
EOR
F002 28
F010 2.14
F004 1
F005 RE
F006 EWF (1990)
** Specifications for petroleum derived hydrocarbon waxes -
** food grade
** Brussels: European Wax Federation
F007 EWF (1990)
** Specifications for petroleum derived hydrocarbon waxes -
** food grade
** Brussels: European Wax Federation
F008 IUC31
F020 1895
EOR
F002 28
F010 2.14
F004 1
F005 RE
F006 Kaufman, J. J. and Weisberger, G. A. (1993)
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** ASTM Manual on significance of tests for petroleum products
** (6th ed). Chapter 10.
F007 Kaufman, J. J. and Weisberger, G. A. (1993)
** Petroleum waxes, including petrolatums.
** ASTM Manual on significance of tests for petroleum products
** (6th ed). Chapter 10.
F008 IUC31
F020 1896
EOR
F002 28

F010 2.14
F004 1
F005 RM
F006
** Physico chemical properties for typical grades of wax and
** petrolatum are shown in the following table (CONCAWE, 1999).
** See also Bennet (1975), Kauffman et al (1993) and EWF
** (1990).
**
**
** Melting Kinematic Oil Carbon Penetration
** Point viscosi
F007
** Physico chemical properties for typical grades of wax and
** petrolatum are shown in the following table (CONCAWE, 1999).
** See also Bennet (1975), Kauffman et al (1993) and EWF
** (1990).
**
**
** Melting Kinematic Oil Carbon Penetration
** Point viscosity content number (25°C)
** (°C) at 100 °C (%m/m) range
** (mm²/sec)
**
** ASTM ASTM ASTM ASTM ASTM
** D127 D445 D721 D2505 D1321
** or or
** D3235 D937*
**
** Slack wax
** 45-85 3-30 2-30 12-85 9-80*
**
** Lower Melt Paraffin Wax
** 43-74 3-10 <2.5 18-75 9-50*
**
** Microcrystalline Wax
** 60-95 10-30 <5 23-85 3-60*
**
** Petrolatum
** 36-60 3-30 >10 12-85 >6
**
** NB * The second value given for penetration was determined
** using meth
F008 IUC31
F020 1897
EOR
F002 28
F010 2.2
F004 2
F005 RE
F006 CONCAWE (1984)
** Assessment and comparison of the composition of food-grade
** white oils and waxes manufactured from petroleum by
** catalytic hydrogenation versus conventional treatment.
** Report No. 84/60
** CONCAWE, Den Haag. August 1984
F007 CONCAWE (1984)

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**   Assessment and comparison of the composition of food-grade
**   white oils and waxes manufactured from petroleum by
**   catalytic hydrogenation versus conventional treatment.
**   Report No. 84/60
**   CONCAWE, Den Haag. August 1984
F008 IUC31
F020 1898
EOR
F002 28
F010 2.2
F004 2
F005 RE
F006 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F007 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F020 3976
EOR
F002 28
F010 2.2
F004 2
F005 RM
F006 In a survey of the composition of food grade waxes and oils
**   the boiling range for paraffin wax was reported to be
**   350-485°C. Microcrystalline waxes boiled in excess of 500
**   °C.
**   While boiling points for slack wax and petrolatum are not availa
F007 In a survey of the composition of food grade waxes and oils
**   the boiling range for paraffin wax was reported to be
**   350-485°C. Microcrystalline waxes boiled in excess of 500
**   °C.
**   While boiling points for slack wax and petrolatum are not available,
*    because their constituent hydrocarbons are produced from vacuum
*    distillation, they will have boiling points above 300°C.
F008 IUC31
F020 1899
EOR
F002 28
F010 2.3.1
F004 1
F005 RM
F006 Not relevant
F007 Not relevant
F008 IUC31
F020 1900
EOR
F002 28
F010 2.4
F004 1
F005 RM
F006 All the materials in the category are solid or semi-solid at room
*    temperature.  Any vapor pressure attributable to these materials would be
*    from the oil component of the material (if it is present).  As discussed
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*    in the Lubricating Oil Base
F007 All the materials in the category are solid or semi-solid at room
*    temperature.  Any vapor pressure attributable to these materials would be
*    from the oil component of the material (if it is present).  As discussed
*    in the Lubricating Oil Basestocks test plan, the vapor pressures  of
*    lubricating base oils are expected to be negligible and have been
*    determined in one study to be 1.7 x 10-4 Pa.
F020 3977
EOR
F002 28
F010 2.5
F004 2
F005 RE
F006 Meylan, M, SRC 1994-1999.
**   LOGKOWWIN is contained in the computer program EPIWIN
**   (Estimate ver. 3.04), available from Syracuse Research Corp.
F007 Meylan, M, SRC 1994-1999.
**   LOGKOWWIN is contained in the computer program EPIWIN
**   (Estimate ver. 3.04), available from Syracuse Research Corp.
F008 IUC31
F020 1901
EOR
F002 28
F010 2.5
F004 2
F005 RM
F006 As hydrocarbon number increases above C13, as is the case
**   for the majority of the wax constituents, Log P values >6
**   are predicted. Substances having Log P estimates greater
**   than 6 are characterized by extremely large molecular weight
**   and su
F007 As hydrocarbon number increases above C13, as is the case
**   for the majority of the wax constituents, Log P values >6
**   are predicted. Substances having Log P estimates greater
**   than 6 are characterized by extremely large molecular weight
**   and subsequent hydrophobicity, therefore no significant
**   aqueous exposures or bioaccumulation are expected to occur.
F008 IUC31
F020 1902
EOR
F002 28
F010 2.5
F004 2
F005 RS
F006 Octanol-water partition coefficients (log P or Kow) were
**   modeled with isomers of the lowest molecular weight
**   component (C13 hydrocarbons) in waxes. These partitioning
**   estimates are characteristic of only a small fraction of
**   component molecu
F007 Octanol-water partition coefficients (log P or Kow) were
**   modeled with isomers of the lowest molecular weight
**   component (C13 hydrocarbons) in waxes. These partitioning
**   estimates are characteristic of only a small fraction of
**   component molecules in a given wax. Because of the diversity
**   of compounds encompassing waxes, it is not feasible to model
**   the physicochemical endpoints for each potential compound.
**   Since molecular weight and structural conformation
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**   determines in large part the solubility and vapor pressure
**   characteristics of the hydrocarbons, modeling focused on the
**   lower molecular weight hydrocarbons.  These would be
**   selected C13 and C20 hydrocarbons since waxes consist mostly
**   of C20 to C85 compounds, with some minimal percent of C13
**   through C20 hydrocarbons.  Therefore, the majority of the
**   physicochemical modeling was performed on various
**   paraffinic, naphthenic and aromatic representatives
**   containing 13 and C20 carbon atoms.
**   The Log pow ranges from 4.7 to >/= to 6.7
F008 IUC31
F020 1903
EOR
F002 28
F010 2.6.1
F004 1
F005 RE
F006 CONCAWE (2001)
**   Environmental classification of petroleum substances -
**   Summary data and rationale.
**   Report 01/54
**   CONCAWE, Brussels
F007 CONCAWE (2001)
**   Environmental classification of petroleum substances -
**   Summary data and rationale.
**   Report 01/54
**   CONCAWE, Brussels
F008 IUC31
F020 1904
EOR
F002 28
F010 2.6.1
F004 1
F005 RM
F006 The water solubility of waxes cannot be determined due to
**   their complex mixture characteristics.  Therefore, the water
**   solubility of individual C13 hydrocarbons was modeled. The
**   highest solubilities would be exhibited by only a small
**   fracti
F007 The water solubility of waxes cannot be determined due to
**   their complex mixture characteristics.  Therefore, the water
**   solubility of individual C13 hydrocarbons was modeled. The
**   highest solubilities would be exhibited by only a small
**   fraction of the hydrocarbon molecules present in waxes.
**   Increasing carbon number results in rapidly decreasing
**   solubility, so that the most-soluble (predominantly
**   methyl-substituted diaromatic) C18 and C20 analogues yield
**   model values of 0.01195 and 0.00125 mg/l, respectively.
**   Higher molecular weight (higher carbon number) components
**   are even less water soluble. Based on water solubility
**   modeling for C13 components of complex mixtures, aqueous
**   solubilities of these waxes are typically much less than 1
**   ppm, due to differential partitioning of components between
**   the aqueous and organic phases.
F008 IUC31
F020 1905
EOR
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F002 28
F010 2.8
F004 1
F005 RM
F006 Not relevant
F007 Not relevant
F008 IUC31
F020 1906
EOR
F002 28
F010 3.1.1
F004 1
F005 RE
F006 Meylan, M, SRC 1994-1999.
**   AOPWIN is contained in the computer program EPIWIN (Estimate
**   ver. 3.04), available from Syracuse Research Corp.
F007 Meylan, M, SRC 1994-1999.
**   AOPWIN is contained in the computer program EPIWIN (Estimate
**   ver. 3.04), available from Syracuse Research Corp.
F008 IUC31
F020 1907
EOR
F002 28
F010 3.1.1
F004 1
F005 RM
F006 Although waxes typically have low vapor pressures,
**   volatilization of some lower molecular weight components
**   exhibit relatively high atmospheric oxidation half-lives.
**   Therefore, those compounds that may partition to the
**   atmosphere will be r
F007 Although waxes typically have low vapor pressures,
**   volatilization of some lower molecular weight components
**   exhibit relatively high atmospheric oxidation half-lives.
**   Therefore, those compounds that may partition to the
**   atmosphere will be removed through indirect photochemical
**   degradation. All modeled components exhibited rapid
**   degradation in the atmosphere; the value presented
**   represents both the most volatile component and the longest
**   modeled half-life. All other modeled C13 components had both
**   lower volatility and shorter half-lives.
F008 IUC31
F020 1908
EOR
F002 28
F010 3.1.1
F004 1
F005 RS
F006 t1/2 =  0.913 days (10.96 hr) for most volatile C13
**   component modeled
F007 t1/2 =  0.913 days (10.96 hr) for most volatile C13
**   component modeled
F008 IUC31
F020 1909
EOR
F002 28
F010 3.1.2
```

F004 1
F005 RE
F006 Harris, J.C. 1982.
** Rate of Hydrolysis. In Handbook of Chemical Property
** Estimation Methods. p. 7-6.
** W. J. Lyman, W.F. Reehl and D.H. Rosenblatt, eds.
** McGraw-Hill Book Company, New York, NY, USA.
F007 Harris, J.C. 1982.
** Rate of Hydrolysis. In Handbook of Chemical Property
** Estimation Methods. p. 7-6.
** W. J. Lyman, W.F. Reehl and D.H. Rosenblatt, eds.
** McGraw-Hill Book Company, New York, NY, USA.
F008 IUC31
F020 1910
EOR
F002 28
F010 3.1.2
F004 1
F005 RM
F006 Hydrolysis of an organic chemical is the transformation
** process in which a water molecule or hydroxide ion reacts to
** form a new carbon-oxygen bond. Chemicals that have a
** potential to hydrolyze include alkyl halides, amides,
** carbamates, carb
F007 Hydrolysis of an organic chemical is the transformation
** process in which a water molecule or hydroxide ion reacts to
** form a new carbon-oxygen bond. Chemicals that have a
** potential to hydrolyze include alkyl halides, amides,
** carbamates, carboxylic acid esters and lactones, epoxides,
** phosphate esters, and sulfonic acid esters. Materials in the
** waxes category are not subject to hydrolysis, as they lack
** these reactive groups.
F008 IUC31
F020 1911
EOR
F002 28
F010 3.3.1
F004 1
F005 RE
F006 Mackay, D, A. DiGuardo, S. Paterson, & C. Cowan, EQC Model,
** ver. 1.01, 1997, available from the Environmental Modelling
** Centre, Trent University, Canada.
F007 Mackay, D, A. DiGuardo, S. Paterson, & C. Cowan, EQC Model,
** ver. 1.01, 1997, available from the Environmental Modelling
** Centre, Trent University, Canada.
F008 IUC31
F020 1912
EOR
F002 28
F010 3.3.1
F004 1
F005 RM
F006 Fugacity-based computer modeling indicated that the majority
** of high molecular weight hydrocarbons with carbon numbers of
** C20 and greater in waxes would be distributed to soil.
** Percent distribution estimates were modeled with C13 to C29
** bra

F007 Fugacity-based computer modeling indicated that the majority
** of high molecular weight hydrocarbons with carbon numbers of
** C20 and greater in waxes would be distributed to soil.
** Percent distribution estimates were modeled with C13 to C29
** branched paraffins as this class of wax hydrocarbons shows
** the greater distribution to air. Aromatic compounds with
** carbon numbers from C13 through C85 will partition
** principally to soil. Linear paraffins and naphthenes
** distribute to both soil and air, with increasing
** partitioning to soil for hydrocarbons greater than C20 as
** vapor pressure decreases. Physical properties input are
** those calculated by the EPIWIN Estimation 3.04 program and
** included in this summary. The default model assumptions were used when
* performing the fugacity estimates. Since the majority of hydrocarbon
* components in waxes are primarily normal paraffins of C20 and greater,
* with moderate to minimal amounts of naphthenics, isoparaffins and trace
* amounts of aromatics, volatility is not a significant fate process for
* these petroleum substances due to negligible vapor pressures at ambient
* temperatures and their high molecular weight. As
** hydrocarbon number increases above C20, partitioning to soil
** is the predominant behavior of these compounds.
F008 IUC31
F020 1913
EOR
F002 28
F010 3.3.1
F004 1
F005 RS
F006 Carbon No. % Distribution
** Iso Air Soil Water Sediment Susp. Biota
** paraffin Sediment
** C13 98 1.9 7E-3 4E-2 8E-3 1E-4
** C18 69 30 4E-4 0.68 2E-2 2E-3 C20 33 65 2E-5
1.4 3E-2 4E-3
** C21 18 80 5E-6 1.8 5E-2 4E-3 C22 12 86 2E-6
1.9 6E-2 4
F007 Carbon No. % Distribution
** Iso Air Soil Water Sediment Susp. Biota
** paraffin Sediment
** C13 98 1.9 7E-3 4E-2 8E-3 1E-4
** C18 69 30 4E-4 0.68 2E-2 2E-3 C20 33 65 2E-5
1.4 3E-2 4E-3
** C21 18 80 5E-6 1.8 5E-2 4E-3 C22 12 86 2E-6
1.9 6E-2 4E-3
** C24 6 92 2E-7 2.1 6E-2 5E-3 C26 1 97 2E-8
2.1 7E-2 5E-3
** C29 0.1 98 9E-10 2.2 7E-2 6E-3
F008 IUC31
F020 1914
EOR
F002 28
F010 3.5
F004 1
F005 RE
F006 Hanstveit, A. O. (1990)
** Inherent Biodegradability of Waxes. TNO-Report No R 90/198b
F007 Hanstveit, A. O. (1990)

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**   Inherent Biodegradability of Waxes. TNO-Report No R 90/198b
F008 IUC31
F020 1915
EOR
F002 28
F010 3.5
F004 1
F005 RM
F006 Paraffin wax residue analysis showed less than 10% parent
**   hydrocarbons and some hydrocarbon enrichment from
**   contaminated soil inoculum after 28 days.
F007 Paraffin wax residue analysis showed less than 10% parent
**   hydrocarbons and some hydrocarbon enrichment from
**   contaminated soil inoculum after 28 days.
F008 IUC31
F020 1916
EOR
F002 28
F010 3.5
F004 1
F005 RS
F006 Degradation % after time 80% of ThCO2 after 28 days;
      87%
**   after 84 days                        (paraffins)
**
**                      66% of ThCO2 after 28 days;                     77%
after 84 days
**                      (intermediate wax)
**
**   Kinetic (for sample, positive and negative
**   controls)                            Reference (so
F007 Degradation % after time 80% of ThCO2 after 28 days;
      87%
**   after 84 days                        (paraffins)
**
**                      66% of ThCO2 after 28 days;                     77%
after 84 days
**                      (intermediate wax)
**
**   Kinetic (for sample, positive and negative
**   controls)                            Reference (sodium acetate) -
             Not Reported
**                      Test substance - 80%                    (paraffin, 28
days), 66%
**                      (intermediate wax, 28days)
**
**   Breakdown Products             No other than residual HCs
F008 IUC31
F020 1917
EOR
F002 28
F010 3.5
F004 1
F005 TC
F006 Inoculum:  Soil was collected from land-farm used by the
**   investigators to treat oil-contaminated soil. Soil contained
**   2200 mg/kg mineral oil (generally at greater retention times
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**   than wax components, based on chromatograms provided in
**   repor
F007 Inoculum:  Soil was collected from land-farm used by the
**   investigators to treat oil-contaminated soil. Soil contained
**   2200 mg/kg mineral oil (generally at greater retention times
**   than wax components, based on chromatograms provided in
**   report), and was a sandy loam comprising 68% sand, 14.2%
**   clay and 10.2% silt with 5.4% OC. Elevated levels of heavy
**   metals were measured in the soil but not considered to be
**   inhibitory to the test. Soil was suspended in mineral medium
**   prior to distribution to test vessels at a loading rate of
**   approximately 80 mg/l. No microbial enumeration was
**   undertaken but performance of the inoculum in degrading a
**   reference standard (sodium acetate at 100 mg/l) provided
**   evidence of inoculum adequacy.
**
**   Concentration of test chemical: Test substance loading was
**   approximately 20 mg/l of medium.
**
**   Temp of incubation: 20 + 2ºC
**
**   Dosing procedure:  Each 2-liter vessel contained 1 liter of
**   inoculated medium. The wax was dissolved in heated carbon
**   tetrachloride, then the solution applied to glass fiber
**   filters (13 mm) to obtain about 20 mg wax/filter after
**   evaporation of the solvent. One filter was added to each
**   test material vessel. Controls and reference standards also
**   received glass fiber filters to which CCl4 was added and
**   allowed to evaporate.
**
**   Sampling frequency:  Carbon dioxide production was monitored
**   weekly through day 28, and then every other week to day 84.
**   Wax residues were measured only at test termination.
**
**   Controls: Yes (blank and positive controls per guideline);
**   abiotic and toxicity checks were not included.  Sodium
**   acetate was used as the positive control.
**
**   Analytical method: Carbon dioxide production was measured by
**   titrating residual base with 0.1 N HCl. Wax residues were
**   measured by extracting filters with warm heptane and the
**   volume of extract adjusted prior to GC-FID analysis.
**
**   Method of calculating biodegradation:  Wax was assumed to
**   have a mean composition of [CH2] for the purpose of
**   calculating ThCO2 (3.14 mg CO2/mg wax). The report does not
**   include the mechanics of  calculation of the mineralization
**   endpoint. Total hydrocarbon remaining at 84 days was
**   determined by area integration of the chromatograms, and
**   primary biodegradability was determined by comparing the
**   amound of hydrocarbons at the end of the test with the
**   amount on wax-dosed filters prepared at the start of the
**   test.
**
**   Other:  Two grades of paraffin wax, 52/50 and 58/60 were
**   tested; only the 52/50 grade was tested for 84 days, and in
**   all, three tests were carried out for 52/50. Result below
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**   for 28 days is mean of 52/50 average and 58/60 result. An
**   intermediate wax was also tested as noted in results.
**
**   Test substance was incubated in the inoculated mineral
**   medium in sealed vessels containing a vial of 0.4 M NaOH (5
**   ml) suspended in the headspace above the medium (similar to
**   EPA 835-3100). Carbon dioxide evolution resulting from
**   mineralization of the test substance was trapped in the base
**   for periodic quantitation. Base was renewed at each sampling
**   period. GC analysis for parent compound was carried out on
**   the solid phase of the test medium at study termination.
F008 IUC31
F020 1918
EOR
F002 28
F010 3.5
F004 2
F005 RE
F006 Hanstveit, A. O. (1990)
**   Inherent Biodegradability of Waxes. TNO-Report No R 90/198b
F007 Hanstveit, A. O. (1990)
**   Inherent Biodegradability of Waxes. TNO-Report No R 90/198b
F008 IUC31
F020 1919
EOR
F002 28
F010 3.5
F004 2
F005 RM
F006 Wax residue analysis showed 65% parent hydrocarbons (mostly
**   n-alkanes greater than C43) remained after 84 days. Most
**   iso-alkanes were degraded regardless of carbon number.
F007 Wax residue analysis showed 65% parent hydrocarbons (mostly
**   n-alkanes greater than C43) remained after 84 days. Most
**   iso-alkanes were degraded regardless of carbon number.
F008 IUC31
F020 1920
EOR
F002 28
F010 3.5
F004 2
F005 RS
F006 Degradation % after time:      21% of ThCO2 after 28 days;
**                      25% after 84 days
**
**   Kinetic (for sample,
**   positive and negative controls: Reference (sodium acetate) -
**                      Not Reported
**
**                      Test substance - 21% (28d)
**
**   Breakdown Products:            None
F007 Degradation % after time:      21% of ThCO2 after 28 days;
**                      25% after 84 days
**
**   Kinetic (for sample,
**   positive and negative controls: Reference (sodium acetate) -
```

```
**                      Not Reported
**
**                      Test substance - 21% (28d)
**
**   Breakdown Products:            None
F008 IUC31
F020 1921
EOR
F002 28
F010 3.5
F004 2
F005 TC
F006 Inoculum:  Soil was collected from land-farm used by the
**   investigators to treat oil-contaminated soil. Soil contained
**   2200 mg/kg mineral oil (generally at greater retention times
**   than wax components, based on chromatograms provided in
**   repor
F007 Inoculum:  Soil was collected from land-farm used by the
**   investigators to treat oil-contaminated soil. Soil contained
**   2200 mg/kg mineral oil (generally at greater retention times
**   than wax components, based on chromatograms provided in
**   report), and was a sandy loam comprising 68% sand, 14.2%
**   clay and 10.2% silt with 5.4% OC. Elevated levels of heavy
**   metals were measured in the soil but not considered to be
**   inhibitory to the test. Soil was suspended in mineral medium
**   prior to distribution to test vessels at a loading rate of
**   approximately 80 mg/l. No microbial enumeration was
**   undertaken but performance of the inoculum in degrading a
**   reference standard (sodium acetate at 100 mg/l) provided
**   evidence of inoculum adequacy.
**
**   Concentration of test chemical: Test substance loading was
**   approximately 20 mg/l of medium. Temp of incubation: 20 +
**   2ºC
**
**   Dosing procedure:  Each 2-liter vessel contained 1 liter of
**   inoculated medium. The wax was dissolved in heated carbon
**   tetrachloride, then the solution applied to glass fiber
**   filters (13 mm) to obtain about 20 mg wax/filter after
**   evaporation of the solvent. One filter was added to each
**   test material vessel. Controls and reference standards also
**   received glass fiber filters to which CCl4 was added and
**   allowed to evaporate.
**
**   Sampling frequency:  Carbon dioxide production was monitored
**   weekly through day 28, then every other week through day 84.
**   Wax residues were measured at test termination.
**
**   Controls: Yes (blank and positive controls per guideline);
**   abiotic and toxicity checks were not included.  Sodium
**   acetate was used as the positive control.
**
**   Analytical method: Carbon dioxide production was measured by
**   titrating residual base with 0.1 N HCl. Wax residues were
**   measured by extracting filters with warm heptane and the
**   volume of extract adjusted prior to GC-FID analysis.
**
```

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**   Method of calculating biodegradation:  Wax was assumed to
**   have a mean composition of [CH2] for the purpose of
**   calculating ThCO2 (3.14 mg CO2/mg wax). The report does not
**   include the mechanics of  calculation of the mineralization
**   endpoint. Total hydrocarbon remaining at test termination
**   was determined by area integration of the chromatograms, and
**   primary biodegradability was determined by comparing the
**   amound of hydrocarbons at the end of the test with the
**   amount on wax-dosed filters prepared at the start of the
**   test.
**
**   Other: Test substance was incubated in the inoculated
**   mineral medium in sealed vessels containing a vial of 0.4 M
**   NaOH (5 ml) suspended in the headspace above the medium
**   (similar to EPA 835-3100). Carbon dioxide evolution
**   resulting from mineralization of the test substance was
**   trapped in the base for periodic quantitation. Base was
**   renewed at each sampling period. GC analysis for parent
**   compound was carried out on the solid phase of the test
**   medium at study termination.
F008 IUC31
F020 1922
EOR
F002 28
F010 3.5
F004 3
F005 CL
F006 Waxed paper decomposes at about the same rate as unwaxed
**   paper. Soil invertebrates contribute significantly to the
**   decomposition of waxed paper in leaf litter. Decomposition
**   of waxed paper occurs more rapidly during the autumn/winter,
**   when
F007 Waxed paper decomposes at about the same rate as unwaxed
**   paper. Soil invertebrates contribute significantly to the
**   decomposition of waxed paper in leaf litter. Decomposition
**   of waxed paper occurs more rapidly during the autumn/winter,
**   when there is a fresh layer of leaf litter on the ground,
**   than during the spring/summer, when the last fall's leaf
**   litter has been largely reduced to humus.
F008 IUC31
F020 1923
EOR
F002 28
F010 3.5
F004 3
F005 RE
F006 Hanstveit, (1991).
**   A study of the fate of waxed paper materials in a woodland
**   litter layer.
**   TNO Report No. R 90/243a
F007 Hanstveit, (1991).
**   A study of the fate of waxed paper materials in a woodland
**   litter layer.
**   TNO Report No. R 90/243a
F008 IUC31
F020 1924
EOR
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F002 28
F010 3.5
F004 3
F005 RL
F006 Reliable with restriction, since positive control data not
**   reported
F007 Reliable with restriction, since positive control data not
**   reported
F008 IUC31
F020 1925
EOR
F002 28
F010 3.5
F004 3
F005 RS
F006 Decomposition in the 5 mm mesh bag, which were exposed to
**   invertebrates as well as microbes, proceeded at a higher
**   rate than in the 45 µm bags. Decomposition in the 5 mm mesh
**   bags was nearly complete within 13 weeks in the
**   autumn/winter tes
F007 Decomposition in the 5 mm mesh bag, which were exposed to
**   invertebrates as well as microbes, proceeded at a higher
**   rate than in the 45 µm bags. Decomposition in the 5 mm mesh
**   bags was nearly complete within 13 weeks in the
**   autumn/winter test and within 26 weeks in the spring/summer
**   test, while in the 45 µm bags 25 - 50% was still left after
**   6 months, based on visual observation. Wax residue analyses
**   also indicated more rapid degradation in the cold-weather
**   experiment.
**
**   Waxed and non-waxed (control) paper decomposed at the same
**   rate.
**
**   Paraffin wax residue analysis showed after 6 months a
**   complete or nearly complete degradation of the samples in
**   the 5 mm mesh bags (the 52/54 paraffin wax showed 10%
**   residues remaining after the spring/summer experiment and 0%
**   after the autumn/winter experiment.
**
**   In the 45 µm bags, wax residues remaining at the end of the
**   summer exposure were 30 - 50% for the paraffins and
**   intermediate wax, and 60% for the microcrystalline wax.
**   After winter exposure, paraffin wax residues were 10 - 30%
**   of initial, intermediate wax is reported as 80% of initial,
**   and microcrystalline wax residues were 40% of initial. The
**   winter value for the intermediate wax appears incorrect
**   based on the chromatograms, which show smaller peaks for the
**   winter vs the summer analyses (same scale for both).
F008 IUC31
F020 1926
EOR
F002 28
F010 3.5
F004 3
F005 TC
F006 Inoculum: Waxed paper was placed in nylon bags of different
**   mesh size (45 µm or 5 mm) to allow colonization by either

** microbes alone or by microbes and soil fauna. Leaf litter
** served as the source of the inoculum, and was placed in a
** layer
F007 Inoculum: Waxed paper was placed in nylon bags of different
** mesh size (45 µm or 5 mm) to allow colonization by either
** microbes alone or by microbes and soil fauna. Leaf litter
** served as the source of the inoculum, and was placed in a
** layer over the mesh bags at the start of the test.
**
** Concentration of test chemical: Approximately 20 mg of wax
** per mesh bag.
**
** Temp of incubation: Ambient forest litter layer
** temperatures. Testing was carried out during two different
** seasons: spring/summer (April - October 1989) and
** autumn/winter (November 1989 - May 1990)
**
** Dosing procedure: Each mesh bag contained four 2 x 2 cm
** squares of waxed paper, which were dried and weighed before
** they were placed in the bags. The squares were arranged in a
** single layer within the bags (10 x 10 cm) to avoid sticking
** together.
**
** Sampling frequency: Samples were retrieved monthly and
** decomposition of the squares was estimated visually. The
** remaining sample material was then removed from the bags,
** cleaned, dried (50 ºC) and weighed.
**
** Controls: Non-waxed paper was used as a negative control.
**
** Analytical method: 1) physical decomposition of paper: Each
** piece of paper was assessed visually according to the scale
** 100%, 75%, 50%, 25%, 5%, and 0% decomposition. 2) Wax
** residues were measured by extracting paper with warm heptane
** and the volume of extract adjusted prior to GC-FID analysis.
** To prevent interference of the analysis by the mesh bags,
** soil particles, and base paper, a cleanup step with aluminum
** oxide was used and as much of the bag material as possible
** was removed before extraction. The squares (or remnants
** thereof) from each treatment were pooled before extraction.
**
** Method of calculating biodegradation: The extent of paper
** decomposition was determined by averaging the visual percent
** decomposition scores of the four squares. The degradation of
** the wax was calculated from the analysis of samples taken at
** the start of the test, combined with analyses of uncoated
** paper and of field blanks for determination of background
** interference. Weight differences were not used as artifacts
** such as soil particles could not be removed from the waxed
** surfaces without removing the wax or destroying the paper.
**
** Other: Two grades of paraffin wax, 52/50 and 58/60,
** intermediate wax, and microcrystalline wax were tested.
F008 IUC31
F020 1927
EOR
F002 28

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F010 3.5
F004 4
F005 CL
F006 Not readily biodegradable; inherently biodegradable and
**   extensively biodegradable in long-term exposures
F007 Not readily biodegradable; inherently biodegradable and
**   extensively biodegradable in long-term exposures
F008 IUC31
F020 1928
EOR
F002 28
F010 3.5
F004 4
F005 RE
F006 American Petroleum Institute
F007 American Petroleum Institute
F008 IUC31
F020 1929
EOR
F002 28
F010 3.5
F004 4
F005 RL
F006 Unable to determine GLP status. Study report is in the form
**   of a memo from which some details are lacking. Same details
**   (e.g., temperature log) are also lacking from the raw data
**   provided with the report.
F007 Unable to determine GLP status. Study report is in the form
**   of a memo from which some details are lacking. Same details
**   (e.g., temperature log) are also lacking from the raw data
**   provided with the report.
F008 IUC31
F020 1930
EOR
F002 28
F010 3.5
F004 4
F005 RS
F006 Degradation % after time:      55 % of ThCO2 after 31 days;
**                      98.5% after 137 days
**
**   Kinetic (for sample,
**   positive and
**   negative controls):            Reference (cellulose) 88.7%
      after
**   31 days
**                      Test substance - 55% (31d);                      98.5%
(137 d)
F007 Degradation % after time:      55 % of ThCO2 after 31 days;
**                      98.5% after 137 days
**
**   Kinetic (for sample,
**   positive and
**   negative controls):            Reference (cellulose) 88.7%
      after
**   31 days
```

```
**                      Test substance - 55% (31d);                    98.5%
(137 d)
F008 IUC31
F020 1931
EOR
F002 28
F010 3.5
F004 4
F005 TC
F006 Inoculum:  Soil was collected from a state park in central
**   NJ, and sewage sludge was obtained from a domestic sewage
**   treatment plant in Pennington, NJ. The sludge was aerated
**   for 30 minutes and allowed to settle for an additional 30
**   minutes
F007 Inoculum:  Soil was collected from a state park in central
**   NJ, and sewage sludge was obtained from a domestic sewage
**   treatment plant in Pennington, NJ. The sludge was aerated
**   for 30 minutes and allowed to settle for an additional 30
**   minutes before the supernatant was withdrawn and filtered
**   through #1 filter paper prior to use as the sewage inoculum.
**   Filtrate was used at a rate of 25 ml/l of test medium
**   (2.5%). Soil was added directly to each test flask at a rate
**   of 0.1 g/l.
**   Concentration of test chemical: Test substance loading was
**   approximately 10 mg carbon/L of medium.
**
**   Temp of incubation: 25 ºC
**
**   Dosing procedure: Test material was added by direct addition
**   of 11.8 mg grated wax to each test flask. Reference material
**   (cellulose) was also weighed (25 mg) and added to the
**   reference flasks to provide 10 mg C/l.
**
**   Sampling frequency:  Carbon dioxide production was monitored
**   after 2, 4, 7, 10, 17, and 24 days, and approximately weekly
**   thereafter through day 137.
**
**   Controls: Yes (blank and positive controls per guideline);
**   abiotic and toxicity checks were not included.  Cellulose
**   was used as the positive control.
**
**   Analytical method: Carbon dioxide produced by mineralization
**   of the test substances was absorbed in 0.2 N KOH solution in
**   cuvettes in the headspace of the test vessels. CO2
**   production was measured by titrating residual base with 0.2
**   N HCl.
**
**   Method of calculating biodegradation:  Wax was assumed to
**   contain 85% carbon for the purpose of calculating ThCO2
**   wax). Average titration volumes at each sampling point were
**   corrected for average blank volumes and then the amount of
**   carbon dioxide produced was divided by ThCO2 to determine
**   percent biodegradation.
F008 IUC31
F020 1932
EOR
F002 28
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F010 3.5
F004 5
F005 RE
F006 American Petroleum Institute
F007 American Petroleum Institute
F008 IUC31
F020 1933
EOR
F002 28
F010 3.5
F004 5
F005 RL
F006 Unable to determine GLP status. Study report is in the form
** of a memo from which some details are lacking. Same details
** (e.g., temperature log) are also lacking from the raw data
** provided with the report.
F007 Unable to determine GLP status. Study report is in the form
** of a memo from which some details are lacking. Same details
** (e.g., temperature log) are also lacking from the raw data
** provided with the report.
F008 IUC31
F020 1934
EOR
F002 28
F010 3.5
F004 5
F005 RS
F006 Degradation % after time: 27 % of ThCO2 after 31 days;
** 67.2% after 137 days
**
** Kinetic (for sample,
** positive and negative
** controls): Reference (cellulose) 88.7%
after 31 days
** Test substance - 27% (31d); 67.2%
(137 d)
F007 Degradation % after time: 27 % of ThCO2 after 31 days;
** 67.2% after 137 days
**
** Kinetic (for sample,
** positive and negative
** controls): Reference (cellulose) 88.7%
after 31 days
** Test substance - 27% (31d); 67.2%
(137 d)
F008 IUC31
F020 1935
EOR
F002 28
F010 3.5
F004 5
F005 TC
F006 Inoculum: Soil was collected from a state park in central
** NJ, and sewage sludge was obtained from a domestic sewage
** treatment plant in Pennington, NJ. The sludge was aerated
** for 30 minutes and allowed to settle for an additional 30
** minutes

F007 Inoculum: Soil was collected from a state park in central
**   NJ, and sewage sludge was obtained from a domestic sewage
**   treatment plant in Pennington, NJ. The sludge was aerated
**   for 30 minutes and allowed to settle for an additional 30
**   minutes before the supernatant was withdrawn and filtered
**   through #1 filter paper prior to use as the sewage inoculum.
**   Filtrate was used at a rate of 25 ml/l of test medium
**   (2.5%). Soil was added directly to each test flask at a rate
**   of 0.1 g/l.
**   Concentration of test chemical: Test substance loading was
**   approximately 10 mg carbon/l of medium.
**
**   Temp of incubation: 25 ºC
**
**   Dosing procedure: Test material was added by direct addition
**   of 11.8 mg grated wax to each test flask. Reference material
**   (cellulose) was also weighed (25 mg) and added to the
**   reference flasks to provide 10 mg C/l.
**
**   Sampling frequency: Carbon dioxide production was monitored
**   after 2, 4, 7, 10, 17, and 24 days, and approximately weekly
**   thereafter through day 137. Controls: Yes (blank and
**   positive controls per guideline); abiotic and toxicity
**   checks were not included. Cellulose was used as the
**   positive control.
**
**   Analytical method: Carbon dioxide produced by mineralization
**   of the test substances was absorbed in 0.2 N KOH solution in
**   cuvettes in the headspace of the test vessels. CO2
**   production was measured by titrating residual base with 0.2
**   N HCl.
**
**   Method of calculating biodegradation: Wax was assumed to
**   contain 85% carbon for the purpose of calculating ThCO2
**   wax). Average titration volumes at each sampling point were
**   corrected for average blank volumes, then the amount of
**   carbon dioxide produced was divided by ThCO2 to determine
**   percent biodegradation.
F008 IUC31
F020 1936
EOR
F002 28
F010 3.5
F004 6
F005 RE
F006 Exxon Biomedical Sciences, Inc. (1995).
**   Ready Biodegradability, Manometric Respirometry.
**   Study #102094A.
F007 Exxon Biomedical Sciences, Inc. (1995).
**   Ready Biodegradability, Manometric Respirometry.
**   Study #102094A.
F008 IUC31
F020 1937
EOR
F002 28
F010 3.5
F004 6

F005 RM
F006 Although this specific slack wax process stream is not among
** the HPV-sponsored materials in this category, the hydrotreating
* procedure (i.e., removal of sulfur) does not substantially alter the
* component hydrocarbon character from the sou
F007 Although this specific slack wax process stream is not among
** the HPV-sponsored materials in this category, the hydrotreating
* procedure (i.e., removal of sulfur) does not substantially alter the
* component hydrocarbon character from the source slack wax material (CAS
* No. 64742-61-6).
F020 3996
EOR
F002 28
F010 3.5
F004 6
F005 RS
F006 By day 28, 40% degradation of the test material was observed
** and indicated that the test material was inherently
** biodegradable. By day 5, >60% biodegradation of positive
** control was observed, which meets the guideline requirement.
** No excur
F007 By day 28, 40% degradation of the test material was observed
** and indicated that the test material was inherently
** biodegradable. By day 5, >60% biodegradation of positive
** control was observed, which meets the guideline requirement.
** No excursions from the protocol were noted.Biodegradation
** was based on net oxygen consumption and the theoretical
** oxygen demand of the test material as calculated using
** results of an elemental analysis of the test material.
**
** % Degradation* Mean % Degradation
** Sample (day 28) (day 28)
** SN 60 50.20, 34.54, 33.92 39.55
** Na Benzoate 82.04; 72.88 77.46
**
** * replicate data
F008 IUC31
F020 1938
EOR
F002 28
F010 3.5
F004 6
F005 TC
F006 Fresh activated sludge was obtained one day prior to test
** initiation, and homogenized in a blender for two minutes.
** After allowing the sample to settle for approximately 30
** minutes, the homogenated supernatant was decanted, avoiding
** carry-o
F007 Fresh activated sludge was obtained one day prior to test
** initiation, and homogenized in a blender for two minutes.
** After allowing the sample to settle for approximately 30
** minutes, the homogenated supernatant was decanted, avoiding
** carry-over of solids. Microbial activity of an aliquot of
** the filtered supernatant was 1E6 CFU/ml which was
** determined using microbial agar dip slides. Activated sludge
** supernatant was added to the test medium at 10 ml/l, and the
** inoculated medium was continuously aerated with CO2-free air

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**   until the next day when the test systems were prepared.
**   Test medium consisted of glass distilled water and mineral
**   salts (phosphate buffer, ferric chloride, magnesium sulfate,
**   calcium chloride). Test vessels were 1L glass flasks located
**   in a waterbath and electronically monitored for oxygen
**   consumption. Test material was tested in triplicate,
**   controls and blanks were tested in duplicate. Test material
**   (Slack wax (petroleum), hydrotreated) concentration was
**   approximately  37 mg/l, equivalent to a theoretical oxygen
**   demand (ThOD) of 127 mg/l.  Test material was weighed onto a
**   Gelman type A/E 13 mm glass fiber filter, which was then
**   added to each respirometer flask. Sodium benzoate (positive
**   control) concentration was 53.54 mg/l, and was added using
**   an aliquot of a stock solution.
**   Test temperature was 22 +/- 1 Deg C. All test vessels were
**   stirred constantly for 28 days using magnetic stir bars and
**   plates.
F008 IUC31
F020 1939
EOR
F002 28
F010 3.5
F004 7
F005 RE
F006 Battersby, N. F, Pack, S. E and Watkinson, R. J. (1992)
**   A correlation between the biodegradability of oil products in the CEC
*    L-33-T-82 and Modified Sturm tests
**   Chemosphere Vol 24, No 12, pp 1989-2000
F007 Battersby, N. F, Pack, S. E and Watkinson, R. J. (1992)
**   A correlation between the biodegradability of oil products in the CEC
*    L-33-T-82 and Modified Sturm tests
**   Chemosphere Vol 24, No 12, pp 1989-2000
F020 3981
EOR
F002 28
F010 3.5
F004 7
F005 RE
F006 Mobil Oil Corporation (1984-1991)
**   Unpublished data cited in
**   CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
F007 Mobil Oil Corporation (1984-1991)
**   Unpublished data cited in
**   CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
F020 3982
EOR
F002 28
F010 3.5
F004 7
F005 RM
F006 To assist in the evaluation of petrolatum and slack waxes, information on
*    two white oils is included in this robust summary
F007 To assist in the evaluation of petrolatum and slack waxes, information on
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*    two white oils is included in this robust summary
F020 3983
EOR
F002 28
F010 3.5
F004 7
F005 RS
F006 Degradation after 28 days was
**    0% for the white oil
**    24% for the technical white oil
F007 Degradation after 28 days was
**    0% for the white oil
**    24% for the technical white oil
F020 3980
EOR
F002 28
F010 3.5
F004 7
F005 TS
F006 Two materials were tested
**    White mineral oil CAS 8042-47-5
**    Technical white oil CAS 8042-47-5
**   The test materials were not characterized any further
F007 Two materials were tested
**    White mineral oil CAS 8042-47-5
**    Technical white oil CAS 8042-47-5
**   The test materials were not characterized any further
F020 3978
EOR
F002 28
F010 4.1
F004 1
F005 RE
F006 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F007 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F020 4731
EOR
F002 28
F010 4.1
F004 1
F005 RL
F006 Results of guideline studies provided in a reliable review dossier
F007 Results of guideline studies provided in a reliable review dossier
F020 4730
EOR
F002 28
F010 4.1
F004 1
F005 RM
F006 Information on base oils is included here because the materials have
*    similar hydrocarbon ranges and also have some structures in common with
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*    waxes. Hence the toxicity to freshwater fish of substances in the waxes
*    category is expected to be
F007 Information on base oils is included here because the materials have
*    similar hydrocarbon ranges and also have some structures in common with
*    waxes. Hence the toxicity to freshwater fish of substances in the waxes
*    category is expected to be similar to the lubricating base oils
*    illustrated herein. Data presented below were selected from the base oil
*    database because they were from highly reliable studies and represented
*    the results of all other base oil testing with fish.
**   These, and more data have been summarized also in the robust summary for
*    Lubricating Oil Basestocks
F020 4739
EOR
F002 28
F010 4.1
F004 1
F005 RS
F006 All studies in the table below were conducted using Oncorhyncus mykiss
**
**   Base oil     Exposure    Endpoint**  Value
**          method*                       (mg/l)
**
**   light paraffinic distillate
**
**                   OWD             LL50       >1 000
**
**   heavy paraf
F007 All studies in the table below were conducted using Oncorhyncus mykiss
**
**   Base oil     Exposure    Endpoint**  Value
**          method*                       (mg/l)
**
**   light paraffinic distillate
**
**                   OWD             LL50       >1 000
**
**   heavy paraffinic distillate
**          OWD         LL50        >1 000
**
**   residual oil
**          OWD         LL50        >1 000
**
**    * OWD=Oil-Water Dispersion
F020 4732
EOR
F002 28
F010 4.1
F004 1
F005 TC
F006 Robust summaries of reports of multiple studies on the acute toxicity of
*    lubricating base oils to fish, invertebrates and algae cited in the
*    CONCAWE (1997) document have been prepared for the Lubricating Base Oils
*    test plan. Those studies f
F007 Robust summaries of reports of multiple studies on the acute toxicity of
*    lubricating base oils to fish, invertebrates and algae cited in the
*    CONCAWE (1997) document have been prepared for the Lubricating Base Oils
*    test plan. Those studies for which the results of invertebrate acute
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*    studies are given above were conducted under GLP and employed test
*    conditions consistent with OECD guideline requirements.
F020 4729
EOR
F002 28
F010 4.1
F004 1
F005 TS
F006 CAS 64741-89-5     solvent refined, light paraffinic distillate
**   CAS 64741-88-4     solvent refined heavy paraffinic distillate
**   CAS 64742-01-4     solvent refined residual oil
F007 CAS 64741-89-5     solvent refined, light paraffinic distillate
**   CAS 64741-88-4     solvent refined heavy paraffinic distillate
**   CAS 64742-01-4     solvent refined residual oil
F020 4738
EOR
F002 28
F010 4.2
F004 1
F005 ME
F006 Statistical method: L(E)C50 by Kooijman (1981)
**
**   [Kooijman, S. A. L. M. (1981)
**    Parametric analyses of mortality rates in bio-assays.
**    Water Res. Vol 17, pp 107-119]
F007 Statistical method: L(E)C50 by Kooijman (1981)
**
**   [Kooijman, S. A. L. M. (1981)
**    Parametric analyses of mortality rates in bio-assays.
**    Water Res. Vol 17, pp 107-119]
F020 4722
EOR
F002 28
F010 4.2
F004 1
F005 RE
F006 Adema, D.M.M. and van den Bos Bakker, G.H. (1986)
**   Aquatic toxicity of compounds that may be carried by ships
**   (Marpol 1973, Annex II). Progress report for 1986 from TNO
**   to the Dutch Ministry of Housing, Physical Planning and
**   Environment.
**   R
F007 Adema, D.M.M. and van den Bos Bakker, G.H. (1986)
**   Aquatic toxicity of compounds that may be carried by ships
**   (Marpol 1973, Annex II). Progress report for 1986 from TNO
**   to the Dutch Ministry of Housing, Physical Planning and
**   Environment.
**   Report No. R 86/326a. Delft: TNO.
F020 4720
EOR
F002 28
F010 4.2
F004 1
F005 RL
F006 Well-documented publication which meets basic scientific principles
F007 Well-documented publication which meets basic scientific principles
F020 4724
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EOR
F002 28
F010 4.2
F004 1
F005 RM
F006 Analytical measurements of test substance concentrations in the exposure
*    solutions were not provided by the authors for each exposure level.
*    Rather, the authors listed data for the test levels near the L(E)C50
*    value.  Results show that in
F007 Analytical measurements of test substance concentrations in the exposure
*    solutions were not provided by the authors for each exposure level.
*    Rather, the authors listed data for the test levels near the L(E)C50
*    value.  Results show that in spite of preparing test solutions and
*    testing in sealed vessels, initial concentrations typically did not
*    achieve the theoretical solubility limit and tended to decline between
*    0-hour and 24/48 hour measurements.
F008 IUC31
F020 1941
EOR
F002 28
F010 4.2
F004 1
F005 RS
F006 Tests were conducted multiple times, and the following L(E)C50 values are
*    either means and 95% confidence intervals of the number of tests
*    indicated, or results of limit tests that were conducted.
**
**          Nominal Conc. L(E)C50, mg/l (# tests)
F007 Tests were conducted multiple times, and the following L(E)C50 values are
*    either means and 95% confidence intervals of the number of tests
*    indicated, or results of limit tests that were conducted.
**
**          Nominal Conc. L(E)C50, mg/l (# tests)                (95%
confidence intervals)
**   Test      S1
**   Compound   mg/l      D. magna      C. marinus      M. bahia
**
**   pentane         38      9.1 (4)         10.5 (3)   10.2 (3)
(8.5-9.7)
*    (9.5-11.6)      (9.3-11.2)
**   isopentane NG2        ~3 4.2 (2)       ~10 (2)     ~10 (2)
**   n-hexane   9.5+4   3.2 (4)          --                   --
(3.0 - 3.4)
**   isohexane  ~13        ~4.2 (3)   ~4.2 (1)    ~4.2 (1)
**   cyclohexane 55       ~2.4 (3)     3.1 (1)     3.1 (1)
(0.1 -
*    7.8)   (1.0 - 9.8)
**   n-heptane   2.7       3.9 (4)    3.1 (1)     2.1 (1)                  (3.7
-
*    4.2)   (1.0 - 9.4)  (1.7 - 2.5)
**   cycloheptane NG       0.74 (4)   ~1.4 (1)    ~1.4 (1)
**   n-octane    0.66   ~S (1)        ~S (5)      ~S (5)
**   iso-octane  NG        ~2.4 (2)    5.4 (1)     2.4 (1)
(4.3
*    - 6.7)
**   n-nonane    ~0.2   ~S (6)        ~S (3)      >S (3)
**   n-decane    0.05   >S (6)        >S (2)      >S (2)
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**   n-undecane  NG        >S          >S (1)    >S (1)
**   n-dodecane  0.004  >S             >S (1)          >S (1)
**   n-tridecane NG        >S          >S (1)          >S (1)
**   n-tetradecane0.002 >S             >S (1)    > S (1)
**
**   1      S = solubility.
**   2      NG = Not Given.
**   3      ~ indicates approximate value.
**   4      + indicates equal to or greater than.
F020 4723
EOR
F002 28
F010 4.2
F004 1
F005 TC
F006 All test solutions were prepared separately by the addition of the
*    nominal amount of test substance to dilution water in a conical flask.
*    Flasks were filled nearly to capacity (minimal headspace), capped with a
*    glass stopper and then stirr
F007 All test solutions were prepared separately by the addition of the
*    nominal amount of test substance to dilution water in a conical flask.
*    Flasks were filled nearly to capacity (minimal headspace), capped with a
*    glass stopper and then stirred for 24 hours with a magnetic stirrer.
*    After stirring, the solutions were permitted to stand for either 4 or 24
*    hours, and the test solutions were decanted from the bottom of the flask
*    into the test vessels.
**
**   Vessels for testing daphnids were 250-ml conical flasks and held 25
*    daphnids during testing.  Flasks were completely filled with test
*    solution (no headspace) and closed with glass stoppers to prevent
*    volatilization. Vessels for testing the gammarids and mysids were 20-ml
*    scintillation vials and each vial held one gammarid or one mysid during
*    testing. Ten vials were used for each test solution. Vials were
*    completely filled with test solution (no headspace) and capped to prevent
*    volatilization.  Tests with daphnids were not renewed during the 48-hour
*    exposure, but tests with gammarids and mysids were renewed with
*    freshly-prepared exposure solutions every 24 hours.
**
**   All test animals were cultured in the laboratory; C. marinus used in
*    testing were young, approximately 5 mm long; M bahia were approximately 4
*    weeks old and 6 mm long; and D. magna were <24 hours old.  Testing was
*    conducted at 20 °C. C. marinus and M. bahia were tested in natural
*    seawater, while D. magna were tested in synthetic freshwater medium
*    having a hardness of approximately 210 mg/l as CaCO3 and a pH ranging
*    from 8.0 to 8.2. Water pH and dissolved oxygen concentrations were
*    monitored during testing (frequency not stated).  The article states that
*    the pH values in all the tests ranged from 7.5 to 8.3, and dissolved
*    oxygen concentrations were always >6.5 mg/l.
**
**   Analytical determinations of test substance concentrations were made by
*    gas chromatography with an apolar capillary column and flame ionization
*    detector.  Identification of specific compounds was made by retention
*    times. Measurements of test substance concentrations were made on samples
*    taken from the D. magna tests at 0-hours (fresh solutions) and 48-hours
*    (old solutions). Solutions analyzed in the C. marinus and M. bahia tests
*    were taken at 0-hours (fresh) and 24 hours (old).  Not all analytical
*    results were quoted, but those closest to the L(E)C50 value were provided
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*    and used to calculate "initial concentration" L(E)C50 values.  Therefore,
*    these were considered by the author to be rough estimates.  The values
*    reported below by the author were based on nominal concentrations.
F020 4721
EOR
F002 28
F010 4.2
F004 2
F005 RE
F006 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F007 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F020 4725
EOR
F002 28
F010 4.2
F004 2
F005 RL
F006 Results of guideline studies provided in a reliable review dossier
F007 Results of guideline studies provided in a reliable review dossier
F020 4728
EOR
F002 28
F010 4.2
F004 2
F005 RM
F006 Information on base oils is included here because the materials have
*    similar hydrocarbon ranges and also have some structures in common with
*    waxes. Hence the toxicity to aquatic invertebrates of substances in the
*    waxes category is expected
F007 Information on base oils is included here because the materials have
*    similar hydrocarbon ranges and also have some structures in common with
*    waxes. Hence the toxicity to aquatic invertebrates of substances in the
*    waxes category is expected to be similar to the lubricating base oils
*    illustrated herein. Data presented below were selected from the base oil
*    database because they were from highly reliable studies and represented
*    the results of all other base oil testing with aquatic invertebrates.
**   These, and more data have been sumarized also in the robust summary for
*    Lubricating Oil Basestocks
F020 4741
EOR
F002 28
F010 4.2
F004 2
F005 RS
F006 Results for a Solvent refined, light  naphthenic distillate
**   These data, originating from Shell, are summarized in CONCAWE (1997).
**
**   Test species Exposure    Endpoint    Value
**                   method                          (mg/l)
**
**
```

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**   Daphnia magna      WA
F007 Results for a Solvent refined, light  naphthenic distillate
**   These data, originating from Shell, are summarized in CONCAWE (1997).
**
**   Test species Exposure    Endpoint    Value
**                  method                          (mg/l)
**
**
**   Daphnia magna      WAF*        EL50        >10 000
**
**   Gammarus pulex     WAF         EL50        >10 000
**    * WAF = Water Accomodated Fraction
F020 4726
EOR
F002 28
F010 4.2
F004 2
F005 TC
F006 Robust summaries of reports of multiple studies on the acute toxicity of
*    lubricating base oils to fish, invertebrates and algae cited in the
*    CONCAWE (1997) document have been prepared for the Lubricating Base Oils
*    test plan. Those studies f
F007 Robust summaries of reports of multiple studies on the acute toxicity of
*    lubricating base oils to fish, invertebrates and algae cited in the
*    CONCAWE (1997) document have been prepared for the Lubricating Base Oils
*    test plan. Those studies for which the results of invertebrate acute
*    studies are given above were conducted under GLP and employed test
*    conditions consistent with OECD guideline requirements.
F020 4727
EOR
F002 28
F010 4.3
F004 1
F005 RE
F006 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F007 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F020 4735
EOR
F002 28
F010 4.3
F004 1
F005 RL
F006 Results of guideline studies provided in a reliable review dossier
F007 Results of guideline studies provided in a reliable review dossier
F020 4736
EOR
F002 28
F010 4.3
F004 1
F005 RM
F006 Information on base oils is included here because the materials have
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*    similar hydrocarbon ranges and also have some structures in common with
*    waxes. Hence the toxicity to algae of substances in the waxes category is
*    expected to be similar to
F007 Information on base oils is included here because the materials have
*    similar hydrocarbon ranges and also have some structures in common with
*    waxes. Hence the toxicity to algae of substances in the waxes category is
*    expected to be similar to the lubricating base oils illustrated herein.
*    Data presented below were selected from the base oil database because
*    they were from highly reliable studies and represented the results of all
*    other base oil testing with algae.
**   These, and more data have been summarized also in the robust summary for
*    Lubricating Oil Basestocks
F020 4740
EOR
F002 28
F010 4.3
F004 1
F005 RS
F006 All studies in the table below were conducted using Scenedesmus
*    subspicatus
**
**   Base oil     Exposure    Endpoint**  Value
**          method*                       (mg/l)
**
**   light paraffinic distillate
**
**          WAF         IrL50       >1 000
**                      IbL50       >1 000
**   heavy paraffini
F007 All studies in the table below were conducted using Scenedesmus
*    subspicatus
**
**   Base oil     Exposure    Endpoint**  Value
**          method*                       (mg/l)
**
**   light paraffinic distillate
**
**          WAF         IrL50       >1 000
**                      IbL50       >1 000
**   heavy paraffinic distillate
**          WAF         IrL50       >1 000
**                      IbL50       >1 000
**
**   residual oil
**          WAF         IrL5050           >1 000
**                      IbL50       >1 000
**    *     WAF = Water Accomodated Fraction
**    **    IrL50 =     Concentration that inhibits growth             (rate)
by 50%
**
**          IbL50 = Concentration that inhibits growth
      (biomass) by 50%
F020 4733
EOR
F002 28
F010 4.3
F004 1
```

F005 TC
F006 Robust summaries of reports of multiple studies on the acute toxicity of
*   lubricating base oils to fish, invertebrates and algae cited in the
*   CONCAWE (1997) document have been prepared for the Lubricating Base Oils
*   test plan. Those studies f
F007 Robust summaries of reports of multiple studies on the acute toxicity of
*   lubricating base oils to fish, invertebrates and algae cited in the
*   CONCAWE (1997) document have been prepared for the Lubricating Base Oils
*   test plan. Those studies for which the results of invertebrate acute
*   studies are given above were conducted under GLP and employed test
*   conditions consistent with OECD guideline requirements.
F020 4734
EOR
F002 28
F010 4.3
F004 1
F005 TS
F006 CAS 64741-89-5   solvent refined, light paraffinic distillate
**   CAS 64741-88-4   solvent refined heavy paraffinic distillate
**   CAS 64742-01-4   solvent refined residual oil
F007 CAS 64741-89-5   solvent refined, light paraffinic distillate
**   CAS 64741-88-4   solvent refined heavy paraffinic distillate
**   CAS 64742-01-4   solvent refined residual oil
F020 4737
EOR
F002 28
F010 4.5.2
F004 1
F005 RL
F006 Results of guideline studies provided in a reliable review dossier
F007 Results of guideline studies provided in a reliable review dossier
F020 4744
EOR
F002 28
F010 4.5.2
F004 1
F005 RM
F006 Information on base oils is included here because the materials have
*   similar hydrocarbon ranges and also have some structures in common with
*   waxes. Hence the toxicity to aquatic invertebrates of substances in the
*   waxes category is expected
F007 Information on base oils is included here because the materials have
*   similar hydrocarbon ranges and also have some structures in common with
*   waxes. Hence the toxicity to aquatic invertebrates of substances in the
*   waxes category is expected to be similar to the lubricating base oils
*   illustrated herein. Data presented below were selected from the base oil
*   database because they were from highly reliable studies and represented
*   the results of all other base oil testing with fish.
**   These, and more data have been summarized also in the robust summary for
*   Lubricating Oil Basestocks
F020 4745
EOR
F002 28
F010 4.5.2
F004 1
F005 RS
F006

```
**   The NOEL for three base oils are shown in the following table
**
**
**   Test material      Exposure    Value
**          method            (mg/l)
**   Solvent refined, heavy paraffinic distillate
**
**          WAF         >1 000
**
**   Hydrotreated, light naphthenic distillate
**
**          WAF         >1
**
**   Solvent
F007
**   The NOEL for three base oils are shown in the following table
**
**
**   Test material      Exposure    Value
**          method            (mg/l)
**   Solvent refined, heavy paraffinic distillate
**
**          WAF         >1 000
**
**   Hydrotreated, light naphthenic distillate
**
**          WAF         >1
**
**   Solvent refined residual oil
**
**          WAF         >1 000
**
**    *     WAF = Water Accomodated Fraction
**
**    **    Value represents the no observable effect             level (NOEL)
F020 4742
EOR
F002 28
F010 4.5.2
F004 1
F005 TC
F006 Robust summaries of reports of multiple studies on the chronic toxicity
*    of lubricating base oils to fish and invertebrates, cited in CONCAWE
*    (1997), have been prepared for the Lubricating Base Oils test plan. Those
*    studies for which the res
F007 Robust summaries of reports of multiple studies on the chronic toxicity
*    of lubricating base oils to fish and invertebrates, cited in CONCAWE
*    (1997), have been prepared for the Lubricating Base Oils test plan. Those
*    studies for which the results of invertebrate chronic studies are given
*    below were conducted under GLP and employed test conditions consistent
*    with OECD guideline requirements.
F020 4743
EOR
F002 28
F010 4.9
F004 1
F005 RE
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F006 Adema, D.M.M. and van den Bos Bakker, G.H. (1986)
** Aquatic toxicity of compounds that may be carried by ships
** (Marpol 1973, Annex II). Progress report for 1986 from TNO
** to the Dutch Ministry of Housing, Physical Planning and
** Environment.
** R
F007 Adema, D.M.M. and van den Bos Bakker, G.H. (1986)
** Aquatic toxicity of compounds that may be carried by ships
** (Marpol 1973, Annex II). Progress report for 1986 from TNO
** to the Dutch Ministry of Housing, Physical Planning and
** Environment.
** Report No. R 86/326a. Delft: TNO.
F008 IUC31
F020 1943
EOR
F002 28
F010 4.9
F004 1
F005 RE
F006 CONCAWE (1997)
** Lubricating oil basestocks
** Product dossier No. 97/108
** CONCAWE, Brussels
F007 CONCAWE (1997)
** Lubricating oil basestocks
** Product dossier No. 97/108
** CONCAWE, Brussels
F008 IUC31
F020 1944
EOR
F002 28
F010 4.9
F004 1
F005 RE
F006 CONCAWE (2001)
** Environmental classification of petroleum substances -
** Summary data and rationale.
** Report 01/54
** CONCAWE, Brussels
F007 CONCAWE (2001)
** Environmental classification of petroleum substances -
** Summary data and rationale.
** Report 01/54
** CONCAWE, Brussels
F008 IUC31
F020 1945
EOR
F002 28
F010 4.9
F004 1
F005 RM
F006 The physical size and number of carbon atoms in petroleum
** waxes and related materials severely limits the ability of
** these materials to be taken up into living organisms. It is
** accepted that the ecotoxicity of alkanes of carbon number
** grea
F007 The physical size and number of carbon atoms in petroleum

```
**   waxes and related materials severely limits the ability of
**   these materials to be taken up into living organisms.  It is
**   accepted that the ecotoxicity of alkanes of carbon number
**   greater than C10 are not acutely toxic to aquatic organisms
**   at their limit of solubility in water (Adema, 1986). The
**   petroleum waxes, containing hydrocarbons greater than C13,
**   would not be expected to cause acute toxicity to aquatic
**   organisms.
**   The results of toxicity tests with lubricant base
**   oils, which have similar hydrocarbon ranges and some
**   structures in common [Sections 4.1., 4.2. and 4.3. above], show no acute
*    toxicity to freshwater fish, invertebrates, or algae and no chronic
*    effects to aquatic life at concentrations below 1 mg/l. (CONCAWE, 1997,
*    2001)
F008 IUC31
F020 1946
EOR
F002 28
F010 4.9
F004 2
F005 RE
F006 Exxon Biomedical Sciences Inc.
**   C. Lee Personal Communication to S. Fraser, Environment
**   Canada 01EMBSI.748;2001EMBSI.ZZJNK; and
**   01EMBSI.749;2001EMBSI.ZZJNK
F007 Exxon Biomedical Sciences Inc.
**   C. Lee Personal Communication to S. Fraser, Environment
**   Canada 01EMBSI.748;2001EMBSI.ZZJNK; and
**   01EMBSI.749;2001EMBSI.ZZJNK
F008 IUC31
F020 1947
EOR
F002 28
F010 4.9
F004 2
F005 RM
F006 In February of 2001 discharge of slack wax to national parks
**   along British Columbia (Canada) coastline occurred during
**   tank washing activities, impacting approximately 100 km of
**   Pacific Rim National Park beach. Canadian Wildlife Service
**   (a
F007 In February of 2001 discharge of slack wax to national parks
**   along British Columbia (Canada) coastline occurred during
**   tank washing activities, impacting approximately 100 km of
**   Pacific Rim National Park beach. Canadian Wildlife Service
**   (a branch of Environment Canada) and the  Department of
**   Fisheries and Oceans biologists agreed that the risk of
**   acute toxicity to aquatic life in the area was minimal based
**   on the low solubility of the components in the wax and given
**   that the BC Parks staff observed no significant
**   environmental impacts. Generally the consensus was that the
**   material was relatively inert and would likely pose little
**   environmental damage.
F008 IUC31
F020 1948
EOR
F002 28
```

F010 4.9
F004 3
F005 RE
F006 Abernathy, S., D. Mackay, L. McCarty (1988).
** Volume fraction correlation for narcosis in aquatic
** organisms: the key role of partitioning,
** Environ Toxicol Chem 7, 469-481
F007 Abernathy, S., D. Mackay, L. McCarty (1988).
** Volume fraction correlation for narcosis in aquatic
** organisms: the key role of partitioning,
** Environ Toxicol Chem 7, 469-481
F008 IUC31
F009 07-01-2002
F020 1949
EOR
F002 28
F010 4.9
F004 3
F005 RE
F006 Adema, D.M.M. (1991)
** The acute aquatic toxicity of alkylbenzenes. Dutch
** contribution to collecting data with respect to Annex II of
** Marpol 1973/1978.
** Progress report no. 1 for 1990 and 1991.
** Report No. R 91/198. Delft: TNO
F007 Adema, D.M.M. (1991)
** The acute aquatic toxicity of alkylbenzenes. Dutch
** contribution to collecting data with respect to Annex II of
** Marpol 1973/1978.
** Progress report no. 1 for 1990 and 1991.
** Report No. R 91/198. Delft: TNO
F008 IUC31
F020 1950
EOR
F002 28
F010 4.9
F004 3
F005 RE
F006 Adema, D.M.M. and van den Bos Bakker, G.H. (1986)
** Aquatic toxicity of compounds that may be carried by ships
** (Marpol 1973, Annex II). Progress report for 1986 from TNO
** to the Dutch Ministry of Housing, Physical Planning and
** Environment.
** R
F007 Adema, D.M.M. and van den Bos Bakker, G.H. (1986)
** Aquatic toxicity of compounds that may be carried by ships
** (Marpol 1973, Annex II). Progress report for 1986 from TNO
** to the Dutch Ministry of Housing, Physical Planning and
** Environment.
** Report No. R 86/326a. Delft: TNO.
F008 IUC31
F020 1951
EOR
F002 28
F010 4.9
F004 3
F005 RE

F006 CEFIC (2000)
** The classification of petroleum solvent streams and related
** complex hydrocarbon solvents for aquatic environmental
** effects under the EU dangerous substances directive.
** Brussels: Hydrocarbon Solvents Producers Association
F007 CEFIC (2000)
** The classification of petroleum solvent streams and related
** complex hydrocarbon solvents for aquatic environmental
** effects under the EU dangerous substances directive.
** Brussels: Hydrocarbon Solvents Producers Association
F008 IUC31
F020 1952
EOR
F002 28
F010 4.9
F004 3
F005 RE
F006 CONCAWE (1997)
** Lubricating oil basestocks
** Product dossier No. 97/108
** CONCAWE, Brussels
F007 CONCAWE (1997)
** Lubricating oil basestocks
** Product dossier No. 97/108
** CONCAWE, Brussels
F008 IUC31
F020 1953
EOR
F002 28
F010 4.9
F004 3
F005 RE
F006 Donkin, P., J. Widdows, S.V. Evans, M.D. Brinsley (1991).
** QSARs for the sublethal response of marine mussels (Mytilus
** edulus) Sci Tot Environ 109/110, 461-474
F007 Donkin, P., J. Widdows, S.V. Evans, M.D. Brinsley (1991).
** QSARs for the sublethal response of marine mussels (Mytilus
** edulus) Sci Tot Environ 109/110, 461-474
F008 IUC31
F020 1954
EOR
F002 28
F010 4.9
F004 3
F005 RE
F006 EU (1996)
** Technical guidance document in support of Commission
** Directive 93/67/EEC on risk assessment for new notified
** substances and Commission Regulation (EC) 1488/94 on risk
** assessment for existing substances. Part IV, Chapter 4: Use
** of
F007 EU (1996)
** Technical guidance document in support of Commission
** Directive 93/67/EEC on risk assessment for new notified
** substances and Commission Regulation (EC) 1488/94 on risk
** assessment for existing substances. Part IV, Chapter 4: Use
** of quantitative structure activity relationships (QSARs) in

**   risk assessment. Luxembourg Office for Official Publications
**   of the European Communities
F008 IUC31
F020 1955
EOR
F002 28
F010 4.9
F004 3
F005 RE
F006 McCarty, L.S. et al (1991)
**   Interpreting aquatic toxicity QSARs: the significance of
**   toxic body residues at the pharmacologic endpoint.
**   In: Hermens, J.L.M. and Opperhuizen, A. (Eds).
**   QSAR in environmental toxicology. Volume IV, p. 515-525.
F007 McCarty, L.S. et al (1991)
**   Interpreting aquatic toxicity QSARs: the significance of
**   toxic body residues at the pharmacologic endpoint.
**   In: Hermens, J.L.M. and Opperhuizen, A. (Eds).
**   QSAR in environmental toxicology. Volume IV, p. 515-525.
**   Amsterdam: Elsevier.
F008 IUC31
F020 1956
EOR
F002 28
F010 4.9
F004 3
F005 RM
F006 The values of log Kow for individual hydrocarbons increase
**   with increasing carbon number within homologous series of
**   generic types. Quantitative structure activity relationships
**   (QSAR), relating log Kow values of single hydrocarbons to
**   toxi
F007 The values of log Kow for individual hydrocarbons increase
**   with increasing carbon number within homologous series of
**   generic types. Quantitative structure activity relationships
**   (QSAR), relating log Kow values of single hydrocarbons to
**   toxicity, show that water solubility decreases more rapidly
**   with increasing Kow than does the concentration causing
**   effects (Abernathy, et al, 1988; Donkin, et al, 1991). This
**   relationship varies somewhat with species, but it follows
**   that there is a log Kow limit for hydrocarbons, above which,
**   they will not exhibit acute toxicity; this limit is at a log
**   Kow value of about 4 to 5 (Abernathy, et al, 1988; Donkin,
**   et al, 1991). It has been confirmed experimentally that for
**   fish and invertebrates, paraffinic hydrocarbons with a
**   carbon number of 10 or higher (log Kow >5) show no acute
**   toxicity (Adema, 1986) and that alkylbenzenes with a carbon
**   number of 14 or greater (log Kow >5) similarly show no acute
**   toxicity (Adema, 1991) From these well-demonstrated
**   solubility 'cut-offs' for acute toxicity of hydrocarbon
**   substances, which directly relate to their physico-chemical
**   properties, it is clear that the same should hold for
**   complex petroleum substances. QSAR equations for chronic
**   toxicity also suggest that there should be a point where
**   hydrocarbons with high log Kow values become so insoluble in
**   water that they will not cause chronic toxicity, that is,
**   that there is also a solubility cut-off for chronic toxicity

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**   (McCarty, L.S. et al, 1991; European Union,1996). Thus,
**   paraffinic hydrocarbons with carbon numbers of greater than
**   14 (log Kow >7.3) should show no measurable chronic
**   toxicity. The existence of this cut-off for chronic toxicity
**   is supported for petroleum substances by the numerous
**   chronic toxicity studies reported on lubricant base oils,
**   which demonstrate that for these substances which are
**   composed primarily of alkanes and naphthenes of C15 and
**   greater, no evidence of chronic toxicity is seen (Concawe,
**   1997). Further evidence to support this generalisation is
**   provided by a lack of chronic toxicity for hydrocarbon based
**   solvents (CEFIC, 2000)
**   Representative chronic aquatic toxicity data for selected base oils
*    presented in the CONCAWE (1997) review are summarized in 4.5.2 above
**
F008 IUC31
F020 1957
EOR
F002 28
F010 5.1.1
F004 1
F005 ME
F006 Paraffin wax was administered orally as a solution in
**   arachis oil to groups of 5 male and 5 female rats at dose
**   levels of 1 and 5 g/Kg.
**   The rats were observed for clinical signs of toxicity for
**   the following 7 days. On the seventh day the a
F007 Paraffin wax was administered orally as a solution in
**   arachis oil to groups of 5 male and 5 female rats at dose
**   levels of 1 and 5 g/Kg.
**   The rats were observed for clinical signs of toxicity for
**   the following 7 days. On the seventh day the animals were
**   weighed, then killed and autopsied.
F008 IUC31
F020 1958
EOR
F002 28
F010 5.1.1
F004 1
F005 RE
F006 IBR (1976)
**   Akute Toxizitotsprufung von "R 9107" nach oraler applikation
**   an der ratte
**   International Bio-Research Inc. Report No. 1-4-195/1-76
F007 IBR (1976)
**   Akute Toxizitotsprufung von "R 9107" nach oraler applikation
**   an der ratte
**   International Bio-Research Inc. Report No. 1-4-195/1-76
F008 IUC31
F020 1959
EOR
F002 28
F010 5.1.1
F004 1
F005 RL
F006 Although there is no indication that the study was carried
**   out according to GLP, it nevertheless is a reliable study
```

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**   and full details are provided in the laboratory report.
F007 Although there is no indication that the study was carried
**   out according to GLP, it nevertheless is a reliable study
**   and full details are provided in the laboratory report.
F008 IUC31
F020 1960
EOR
F002 28
F010 5.1.1
F004 1
F005 RS
F006 There were no clinical signs of toxicity during the seven
**   day observation period and growth rates were normal. There
**   were no mortalities and no macroscopic changes were observed
**   at autopsy.
**   The LD50 was found to be greater than 5g/Kg.
F007 There were no clinical signs of toxicity during the seven
**   day observation period and growth rates were normal. There
**   were no mortalities and no macroscopic changes were observed
**   at autopsy.
**   The LD50 was found to be greater than 5g/Kg.
F008 IUC31
F020 1961
EOR
F002 28
F010 5.1.1
F004 1
F005 TS
F006 R 9071 is described as paraffin wax, without further characterization.
**   R 9071 was prepared as solutions in arachis oil for oral dosing.
**   Two concentrations (20 and 100 mg/ml) were prepared for the
**   two dose levels tested.
F007 R 9071 is described as paraffin wax, without further characterization.
**   R 9071 was prepared as solutions in arachis oil for oral dosing.
**   Two concentrations (20 and 100 mg/ml) were prepared for the
**   two dose levels tested.
F008 IUC31
F020 1962
EOR
F002 28
F010 5.1.1
F004 2
F005 ME
F006 Microcrystalline  wax was administered orally as a solution
**   in arachis oil to groups of 5 male and 5 female rats at dose
**   levels of 1 and 5 g/Kg.
**   The rats were observed for clinical signs of toxicity for
**   the following 7 days. On the seventh
F007 Microcrystalline  wax was administered orally as a solution
**   in arachis oil to groups of 5 male and 5 female rats at dose
**   levels of 1 and 5 g/Kg.
**   The rats were observed for clinical signs of toxicity for
**   the following 7 days. On the seventh day the animals were
**   weighed, then killed and autopsied.
F008 IUC31
F020 1963
EOR
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F002 28
F010 5.1.1
F004 2
F005 RE
F006 IBR (1976)
** Akute Toxizitotsprufung von "R 9269" nach oraler Applikation
** an der ratte.
** International Bio-Research Inc. Report No. 1-4-195/2-76.
F007 IBR (1976)
** Akute Toxizitotsprufung von "R 9269" nach oraler Applikation
** an der ratte.
** International Bio-Research Inc. Report No. 1-4-195/2-76.
F008 IUC31
F020 1964
EOR
F002 28
F010 5.1.1
F004 2
F005 RL
F006 Although there is no indication that the study was carried
** out according to GLP, it nevertheless is a reliable study
** and full details are provided in the laboratory report.
F007 Although there is no indication that the study was carried
** out according to GLP, it nevertheless is a reliable study
** and full details are provided in the laboratory report.
F008 IUC31
F020 1965
EOR
F002 28
F010 5.1.1
F004 2
F005 RS
F006 There were no clinical signs of toxicity during the seven
** day observation period and growth rates were normal. There
** were no mortalities and no macroscopic changes were observed
** at autopsy.
** The LD50 was found to be greater than 5g/Kg.
F007 There were no clinical signs of toxicity during the seven
** day observation period and growth rates were normal. There
** were no mortalities and no macroscopic changes were observed
** at autopsy.
** The LD50 was found to be greater than 5g/Kg.
F008 IUC31
F020 1966
EOR
F002 28
F010 5.1.1
F004 2
F005 TS
F006 R 9269 is described as microcrystalline wax, without further
* characterization.
** R 9269 was prepared as solutions in arachis oil for oral dosing.
** Two concentrations (20 and 100 mg/ml) were prepared for the
** two dose levels tested.
F007 R 9269 is described as microcrystalline wax, without further
* characterization.
** R 9269 was prepared as solutions in arachis oil for oral dosing.

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**   Two concentrations (20 and 100 mg/ml) were prepared for the
**   two dose levels tested.
F008 IUC31
F020 1967
EOR
F002 28
F010 5.1.3
F004 1
F005 ME
F006 Method is not described.
F007 Method is not described.
F008 IUC31
F020 1968
EOR
F002 28
F010 5.1.3
F004 1
F005 RE
F006 Elder, R (1984)
**   Final Report on the Safety Assessment of Fossil and
**   Synthetic Waxes
**   Editor R. Elder
**   J. Am. College of Toxicology Volume 3, number 4, pages 43-99
F007 Elder, R (1984)
**   Final Report on the Safety Assessment of Fossil and
**   Synthetic Waxes
**   Editor R. Elder
**   J. Am. College of Toxicology Volume 3, number 4, pages 43-99
F008 IUC31
F009 22-07-2002
F020 1969
EOR
F002 28
F010 5.1.3
F004 1
F005 RL
F006 This information is taken from a published safety review
**   conducted by an expert panel. Few experimental details
**   are provided and the quality of the studies and the panel's
**   conclusions cannot be verified.
F007 This information is taken from a published safety review
**   conducted by an expert panel. Few experimental details
**   are provided and the quality of the studies and the panel's
**   conclusions cannot be verified.
F008 IUC31
F020 1970
EOR
F002 28
F010 5.1.3
F004 1
F005 RM
F006 The report does not provide sufficient information to fully
**   evaluate the study.
F007 The report does not provide sufficient information to fully
**   evaluate the study.
F008 IUC31
F020 1971
```

EOR
F002 28
F010 5.1.3
F004 1
F005 TS
F006 Paraffin wax administered as a 50% solution in petrolatum.
F007 Paraffin wax administered as a 50% solution in petrolatum.
F008 IUC31
F020 1972
EOR
F002 28
F010 5.10
F004 2
F005 RE
F006 Conti, A., Manzini, B. M., Schiavi, M. E. and Motolese, A.
** (1995)
** Sensitization to white petrolatum used as a vehicle for
** patch testing.
** Contact Dermatitis Volume 33, pages 201-202.
F007 Conti, A., Manzini, B. M., Schiavi, M. E. and Motolese, A.
** (1995)
** Sensitization to white petrolatum used as a vehicle for
** patch testing.
** Contact Dermatitis Volume 33, pages 201-202.
F008 IUC31
F020 1973
EOR
F002 28
F010 5.10
F004 2
F005 RE
F006 Dooms-Goosens, A. and Degreef, H. (1983)
** Contact allergy to petrolatums (1) Sensitizing capacity of
** different brands of yellow and white petrolatums.
** Contact Dermatitis Volume 9, Pages 175-185.
F007 Dooms-Goosens, A. and Degreef, H. (1983)
** Contact allergy to petrolatums (1) Sensitizing capacity of
** different brands of yellow and white petrolatums.
** Contact Dermatitis Volume 9, Pages 175-185.
F008 IUC31
F020 1974
EOR
F002 28
F010 5.10
F004 2
F005 RE
F006 Fisher, A. A. (1981)
** Cutaneous reactions to petrolatum
** Cutis, Volume 28 Pages 23--, 24, 31, 57 & 93.
F007 Fisher, A. A. (1981)
** Cutaneous reactions to petrolatum
** Cutis, Volume 28 Pages 23--, 24, 31, 57 & 93.
F008 IUC31
F020 1975
EOR
F002 28
F010 5.10

F004 2
F005 RE
F006 Frankel, E. B. (1985)
** Letter to the editor: Acne secondary to white petrolatum use
** Arch. Dermatol. Vol. 121, pages 589-590.
F007 Frankel, E. B. (1985)
** Letter to the editor: Acne secondary to white petrolatum use
** Arch. Dermatol. Vol. 121, pages 589-590.
F008 IUC31
F020 1976
EOR
F002 28
F010 5.10
F004 2
F005 RM
F006 Despite the widespread use of petrolatum for many years as a
** vehicle in human skin patch testing, isolated cases of
** allergy to petrolatum have been reported.
** Neverthelesss, petrolatum is still considered to be a good
** vehicle for patch testi
F007 Despite the widespread use of petrolatum for many years as a
** vehicle in human skin patch testing, isolated cases of
** allergy to petrolatum have been reported.
** Neverthelesss, petrolatum is still considered to be a good
** vehicle for patch testing. Fisher has concluded that
** although allergic reactions to petrolatum are rare, white,
** and not yellow petrolatum should be used as a vehicle in
** human skin patch testing.
F008 IUC31
F020 1977
EOR
F002 28
F010 5.10
F004 2
F005 RM
F006 Petrolatum
F007 Petrolatum
F008 IUC4
F009 28-01-2003
F020 1978
EOR
F002 28
F010 5.10
F004 3
F005 RE
F006 Hendricks, N. V. et al (1959)
** Cancer of the scrotum in wax pressmen
** I. Epidemiology. AMA Arch. Ind. Health Vol 19, pp 524-529
F007 Hendricks, N. V. et al (1959)
** Cancer of the scrotum in wax pressmen
** I. Epidemiology. AMA Arch. Ind. Health Vol 19, pp 524-529
F008 IUC31
F020 1979
EOR
F002 28
F010 5.10
F004 3

F005 RE
F006 Lione, J. G. and Denholm, J. S. (1959)
** Cancer of the scrotum in wax pressmen
** II. Clinical observations. AMA Arch. Ind. Health Vol 19, pp
** 530-539
F007 Lione, J. G. and Denholm, J. S. (1959)
** Cancer of the scrotum in wax pressmen
** II. Clinical observations. AMA Arch. Ind. Health Vol 19, pp
** 530-539
F008 IUC31
F020 1980
EOR
F002 28
F010 5.10
F004 3
F005 RM
F006 Slack wax
F007 Slack wax
F008 IUC4
F009 28-01-2003
F020 1981
EOR
F002 28
F010 5.10
F004 3
F005 RM
F006 There are no published reports of acute effects in humans
** with slack waxes, but they are expected to be essentially
** non-toxic because both the residual oil and the wax
** components themselves are not acutely toxic.
**
** There have been several re
F007 There are no published reports of acute effects in humans
** with slack waxes, but they are expected to be essentially
** non-toxic because both the residual oil and the wax
** components themselves are not acutely toxic.
**
** There have been several reports of human occupational cancer
** amongst wax pressmen, during the preparation of paraffin wax
** (Hendricks et al, 1959; Lione and Denholm, 1959). In the
** process of wax pressing the unrefined or poorly refined oil
** was chilled and the solidified crude wax (slack wax) removed
** from the viscous oil on filter presses. This crude wax may
** have contained as much as 20-40% unrefined/poorly refined
** oil, which was reduced to less than 0.5% in subsequent
** processing. It should be noted that wax pressing is no
** longer used as a process and has been replaced by more
** modern techniques.
F008 IUC31
F020 1982
EOR
F002 28
F010 5.10
F004 4
F005 RE
F006 Elder, R (1984)
** Final Report on the Safety Assessment of Fossil and

** Synthetic Waxes
** Editor R. Elder
** J. Am. College of Toxicology Volume 3, number 4, pages 43-99
F007 Elder, R (1984)
** Final Report on the Safety Assessment of Fossil and
** Synthetic Waxes
** Editor R. Elder
** J. Am. College of Toxicology Volume 3, number 4, pages 43-99
F008 IUC31
F009 22-07-2002
F020 1983
EOR
F002 28
F010 5.10
F004 4
F005 RE
F006 Halton, D. M. and Piersol, P. (1994)
** Investigations into an outbreak of rashes in a wax coating
** treatment process.
** Appl. Occup. Environ. Hyg. Vol 9, No 12, pp 941-944
F007 Halton, D. M. and Piersol, P. (1994)
** Investigations into an outbreak of rashes in a wax coating
** treatment process.
** Appl. Occup. Environ. Hyg. Vol 9, No 12, pp 941-944
F008 IUC31
F020 1984
EOR
F002 28
F010 5.10
F004 4
F005 RE
F006 Hjorth, N. (1987)
** Diagnostic patch testing.
** In: Marzuli, F. N. and Maibach, H. I. (Eds)
** Dermato-toxicology (3rd edition). Chapter 13, pp 307-317
** Washington DC: Hemisphere Publishing Corp.
F007 Hjorth, N. (1987)
** Diagnostic patch testing.
** In: Marzuli, F. N. and Maibach, H. I. (Eds)
** Dermato-toxicology (3rd edition). Chapter 13, pp 307-317
** Washington DC: Hemisphere Publishing Corp.
F008 IUC31
F020 1985
EOR
F002 28
F010 5.10
F004 4
F005 RM
F006 A review of the clinical studies with two undiluted paraffin
** waxes and formulated products containing various
** concentrations of paraffinic (5-16%) and microcrysatlline
** (4.35-15%) waxes was published (Anon, 1984). These studies
** include a ran
F007 A review of the clinical studies with two undiluted paraffin
** waxes and formulated products containing various
** concentrations of paraffinic (5-16%) and microcrysatlline
** (4.35-15%) waxes was published (Anon, 1984). These studies

** include a range of acute and repeat application tests in
** groups of humans for skin irritation and skin sensitization.
** All products gave, at most, slight erythema and none caused
** skin sensitization.
**
** The widespread use in cosmetic and in cosmetic surgery over
** many years demonstrates the low toxicity of refined waxes
** and many guidelines exist for their safe use (Hjorth, 1987).
** Notwithstanding this, there are occasional reports of
** adverse effects with these products. Subcutaneous deposits,
** often referred to as parafinoma, have been described
** frequently following injection of these materials under the
** skin but these are not normally associated with other
** progressive changes.
**
** There has been one report where an outbreak of skin rashes
** was attributed to occupational exposure to wax fume (Halton
** & Piersol, 1994).
F008 IUC31
F020 1986
EOR
F002 28
F010 5.10
F004 4
F005 RM
F006 Paraffin wax
F007 Paraffin wax
F008 IUC4
F009 28-01-2003
F020 1987
EOR
F002 28
F010 5.2.1
F004 1
F005 RE
F006 Elder, R (1984)
** Final Report on the Safety Assessment of Fossil and
** Synthetic Waxes
** Editor R. Elder
** J. Am. College of Toxicology Volume 3, number 4, pages 43-99
F007 Elder, R (1984)
** Final Report on the Safety Assessment of Fossil and
** Synthetic Waxes
** Editor R. Elder
** J. Am. College of Toxicology Volume 3, number 4, pages 43-99
F008 IUC31
F009 22-07-2002
F020 1988
EOR
F002 28
F010 5.2.1
F004 1
F005 RL
F006 This information is taken from a published safety review
** conducted by an expert panel. Few experimental details
** are provided and the quality of the studies and the panel's
** conclusions cannot be verified.

F007 This information is taken from a published safety review
**   conducted by an expert panel. Few experimental details
**   are provided and the quality of the studies and the panel's
**   conclusions cannot be verified.
F008 IUC31
F020 1989
EOR
F002 28
F010 5.2.1
F004 1
F005 RM
F006 An expert panel on cosmetics reviewed the skin irritation
**   data and reported:
**
**   * An undiluted paraffin wax was non-irritant in a 24 hour
**   occluded patch test in rabbits
**
**   * A microcrystalline wax was slightly irritating in a 24
**
F007 An expert panel on cosmetics reviewed the skin irritation
**   data and reported:
**
**   * An undiluted paraffin wax was non-irritant in a 24 hour
**   occluded patch test in rabbits
**
**   * A microcrystalline wax was slightly irritating in a 24
**   hour occluded patch test
F008 IUC31
F020 1990
EOR
F002 28
F010 5.2.1
F004 1
F005 RS
F006 The report contains the following statement:
**   A sample of 100% paraffin wax was applied full strength
**   under a single closed patch to the skin of 9 rabbits. No
**   irritation developed.
**   Three samples of 50% paraffin in petrolatum were tested in
**   r
F007 The report contains the following statement:
**   A sample of 100% paraffin wax was applied full strength
**   under a single closed patch to the skin of 9 rabbits. No
**   irritation developed.
**   Three samples of 50% paraffin in petrolatum were tested in
**   repeated, open patch applications to 6 rabbits. Two samples
**   produced erythema in four animals that lasted three days,
**   and one produced erythema in one rabbit that lasted two
**   days.
**   No other details are provided.
F008 IUC31
F020 1991
EOR
F002 28
F010 5.2.2
F004 1
F005 RE

F006 Elder, R (1984)
** Final Report on the Safety Assessment of Fossil and
** Synthetic Waxes
** Editor R. Elder
** J. Am. College of Toxicology Volume 3, number 4, pages 43-99
F007 Elder, R (1984)
** Final Report on the Safety Assessment of Fossil and
** Synthetic Waxes
** Editor R. Elder
** J. Am. College of Toxicology Volume 3, number 4, pages 43-99
F008 IUC31
F009 22-07-2002
F020 1992
EOR
F002 28
F010 5.2.2
F004 1
F005 RL
F006 This information is taken from a published safety review
** conducted by an expert panel. Few experimental details
** are provided and the quality of the studies and the panel's
** conclusions cannot be verified.
F007 This information is taken from a published safety review
** conducted by an expert panel. Few experimental details
** are provided and the quality of the studies and the panel's
** conclusions cannot be verified.
F008 IUC31
F020 1993
EOR
F002 28
F010 5.2.2
F004 1
F005 RS
F006 The publication states:
**
** Four 50% solutions of paraffin in petrolatum were each
** instilled into the eyes of six albino rabbits with no rinse.
** Eyes were observed for irritation for three days. Two of the
** samples caused mild irritation in one
F007 The publication states:
**
** Four 50% solutions of paraffin in petrolatum were each
** instilled into the eyes of six albino rabbits with no rinse.
** Eyes were observed for irritation for three days. Two of the
** samples caused mild irritation in one rabbit on day 1; the
** other samples were not irritating.
F008 IUC31
F020 1994
EOR
F002 28
F010 5.4
F004 1
F005 ME
F006 The study consisted of three components each of which is
** described below.
**
** Main study

** Groups of 20 male and 20 female rats were fed diets
** containing one of three different waxes at dietary
** concentrations of 0.002, 0.02, 0.2 & 2.0 % for 90 d
F007 The study consisted of three components each of which is
** described below.
**
** Main study
** Groups of 20 male and 20 female rats were fed diets
** containing one of three different waxes at dietary
** concentrations of 0.002, 0.02, 0.2 & 2.0 % for 90 days.
** Groups of 60 male and 60 females were fed untreated control
** diet for the same period of time.
** A further group of 20 rats of each sex were fed diets
** conatining 2.0 % coconut oil.
**
** Reversal study
** Groups of ten rats of each sex were fed diets containing
** each test material at the 2.0 % level or coconut oil at the
** 2 % level for 90 days, followed by a 28 day period on control
** diet. Groups of 300 rats of each sex were fed control diet
** for the same time period.
**
** Tissue level and reversal study
** Groups of ten rats of each sex were fed either control
** diet, or diet containing 2 % of each of the test materials
** or coconut oil at 2 % for 90 days. At the end of the 90-days, five rats
*   of each sex were sacrificed and their tissues analyzed for mineral
*   hydrocarbons. The remaining five animals of each sex were then fed
*   control diet for a further 28 days, at the end of which they also were
*   sacrificed and their tissues analyzed for mineral hydrocarbons.
**
** The entire study consisted of 40 different treatment groups
** and their organization is summarized in the following table.
**

Group	Treatment*	Main	Reversal	Tissue level and reversal
		M/F	M/F	M/F
1	Control	20/20	10/10	10/10**
2	Control	20/20	10/10	
3	Control	20/20	10/10	
4-27 incl.	groups fed diets containing the mineral oils			
28	LMPW (0.002%)	20/20	10/10	10/10
29	LMPW (0.02%)	20/20	10/10	
30	LMPW (0.2%)	20/20	10/10	
31	LMPW (2.0%)	20/20	10/10	
32	HMPW (0.002%)	20/20	10/10	10/10
33	HMPW (0.02%)	20/20	10/10	
34	HMPW (0.2%)	20/20	10/10	
35	HMPW (2.0%)	20/20	10/10	
36	HSW (0.002%)	20/20	10/10	10/10
37	HSW (0.02%)	20/20	10/10	
38	HSW (0.2%)	20/20	10/10	
39	HSW (2.0%)	20/20	10/10	
40	Coconut (2.0%) oil	20/20	10/10	10/10

**

** * For a description of each wax see "test substance" section
**
** ** 5 animals were for tissue level analysis after 90 days and five
* were for tissue level after a 28 day reversal period.
**
** All animals were monitored for weight, food intakes and
** clinical condition throughout the study. An ophthalmic
** examination was performed prior to treatment and prior to
** necropsy on the animals in the main study and those for the
** study of reversibility.
**
** Necropsy
**
** Main study and reversal animals
**
** A full neropsy was performed and any abnormlities were
** recorded. The following organs were weighed:
** adrenal glands
** brain
** caecum (with and without contents
** heart
** kidney
** liver ovaries
** spleen
** testes
** thymus.
**
** Samples of the following tissues were fixed for subsequent
** microscopic examination:
** adrenal glands, artery (aorta), bladder, brain, caecum,
** colon, cervix uteri, diaphragm, duodenum, epididymis, extra
** orbital lachrymal glands, eye, femur, Harderian gland,
** heart, ileum (including Peyer's patches), jejunum, kidneys,
** liver (representative samples from each lobe), lungs, (with
** main stem bronchi), lymph nodes (axillary, cervical &
** mesenteric), mammary gland (inguinal region), nasal bones,
** nerve (sciatic taken together with surrounding muscle),
** oesophagus, ovaries, pancreas, perirenal fat, pinnae
** (retained for identification only), pituitary, prostate,
** rectum, salivary gland, seminal vesicles, skeletal muscle,
** skin (inguinal region), spinal cord, spleen, sternum,
** stomach, testes, thymus, thyroid/parathyroid glands
** (retained on trachea), tongue, uterine horns, vagina and
** vein (posterior vena cava).
** In addition, samples of the following tissues from the high
** dose and control animals only were retained in formol
** calcium: liver, spleen, small intestine & mesenteric lymph
** node.
**
** Histological examination of tissues
** A microscopic examination was made of H&E sections of all
** preserved tissues from the control and high dose group and
** from the lung, liver, kidney, spleen, small intestine and
** mesenteric lymph node of all other groups. All lung sections

** were examined for evidence of infection.
**
** Hematology
** Blood samples collected from all animals on the main study
** and the reversal study were examined for: total erythrocyte
** count, total leucocyte count, hemoglobin concentration, mean
** cell volume, hematocrit (by calculation), platelet count,
** differential leucocyte count, reticulocyte count and
** prothrombin time.
**
** Clinical chemistry
** Serum from main and reversal study animals was examined for:
** concentrations of glucose, urea, total protein, albumin,
** creatinine, calcium, phosphorus (as phosphate), chloride,
** total bilirubin, sodium and potassium. Activity of the
** following enzymes was also determined: alkaline phosphatase,
** alanine aminotransferase, aspartate aminotransferase and
** gamma glutamyl transferase.
**
** Tissue level and tissue level reversal animals
** Animals designated to provide tissues for analysis for
** mineral hydrocarbons were killed and the following tissues
** weighed and taken for analysis:
** Liver (random samples from the periphery of all lobes)
** Mesenteric lymph nodes (all tissue)
** Kidney (one kidney)
**
** Spleen (approximately half)
** Perirenal fat (random sample)
**
** Tissue analysis for mineral hydrocarbon content
** Tissue samples (approximately 1 g of tissue) from those animals
* designated for tissue analysis were
** homogenized in 70 % KOH solution. The homogenate was
** sonicated for 10 minutes at 60 °C. CCl_4 was added to each
** sample and sonicated for 30 minutes, also at 60 °C,
** occasionally mixing by hand. The layers were separated using
** centrifugation if necessary.
** An aliquot of the lower organic phase was poured onto an
** extraction column (Florosil) and the eluate was collected
** and the column washed with CCl_4 to a known final volume. The
** infra-red absorbance, in the C-H stretching region, of the
** eluate was measured against a CCl_4 background using a
** Fourier Transform infra-red spectrometer. The concentration
** of mineral hydrocarbon in the tissue was calculated by
** comparison with appropriate standards.
**
**
**
** Statistical analysis
** The continuous variable data from the control and test
** groups were tested for normality using the
** Kolmogorov-Smirnov (K.S.) test and homogeneity of variance
** using Bartlett's test.
** Statistical significance was determined to be at $p<0.05$ in a
** K.S. test and at $p<0.01$ in a Bartlett's test. If both test
** were non significant, the control and test groups were

** compared using analysis of variance followed by the least
** significant difference (L.S.D.) test.
** If either test produced a significant result, a suitable
** transformation was attempted. If the transformation data
** resulted in a non-significant Bartlett's test but a
** significant K.S. test, the Wilcoxon Mann-Whitney test was
** used. If the transformed data resulted in a non-significant
** K.S. test but a significant Bartlett's test, an appropriate
** t-test was used, based on whether a pooled variance was
** suitable or not.
** If no suitable transformation could be made, one of the
** above tests was selected as the most appropriate based on
** the nature and distribution of the data.
** Where levels of significance were reported in the tables for
** transformed data the means and standard deviations were
** reported for the untransformed data.
** The results of the Mann-Whitney and t-tests were compared
** with the L.S.D. test. In most cases, the L.S.D test was
** reported. However, if large differences were evident, other
** test results were reported as appropriate unless the data
** was deemed to be highly variable and there was no evidence
** to justify the removal of outliers.
** Incidence data from the histopathogical examination was
** tested for differences between treated and control animals
** using Fischer's exact test. Mann-Whitney tests were
** performed on incidence data graded by severity.
** In all test comparisons, a probability level of p<0.05 in a
** two sided test was taken to indicate statistical
** significance.
F008 IUC31
F020 1995
EOR
F002 28
F010 5.4
F004 1
F005 RE
F006 BIBRA (1992)
** A 90-day feeding study in the rat with six different
** mineral oils [N15 (H), N70 (H), N70 (A), P15 (H), N 10(A)
** and P100 (H)], three different mineral waxes (a low melting
** point wax, a high melting point wax and a high suphur w
F007 BIBRA (1992)
** A 90-day feeding study in the rat with six different
** mineral oils [N15 (H), N70 (H), N70 (A), P15 (H), N 10(A)
** and P100 (H)], three different mineral waxes (a low melting
** point wax, a high melting point wax and a high suphur wax)
** and coconut oil.
** BIBRA Project No: 3.1010
F008 IUC31
F009 12-02-2002
F020 1996
EOR
F002 28
F010 5.4
F004 1
F005 RE
F006 CONCAWE (1993)

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**   White oil and waxes - summary of 90-day studies
**   Report No. 93/56
F007 CONCAWE (1993)
**   White oil and waxes - summary of 90-day studies
**   Report No. 93/56
F008 IUC31
F020 1997
EOR
F002 28
F010 5.4
F004 1
F005 RL
F006 Study conducted to GLP and thoroughly reported.
F007 Study conducted to GLP and thoroughly reported.
F008 IUC31
F020 1998
EOR
F002 28
F010 5.4
F004 1
F005 RM
F006 The purpose of this study was to investigate the biological
**   effects of six mineral oils and three petroleum waxes
**   representative of those used in food processing and food
**   contact applications.
**   This robust summary only describes the results
F007 The purpose of this study was to investigate the biological
**   effects of six mineral oils and three petroleum waxes
**   representative of those used in food processing and food
**   contact applications.
**   This robust summary only describes the results from the
**   three petroleum waxes that were examined.
**   For additional details on the oils see the Lubricating Oil Basestocks
*    Test Plan.
F008 IUC31
F020 1999
EOR
F002 28
F010 5.4
F004 1
F005 RS
F006 Main study
**
**   Microcrystalline waxes (HSW and HMPW)
**
**   Growth rates, food intakes and clinical condition
**   of animals fed either HSW or HMPW were unaffected by
**   exposure
**   No effects were observed at necropsy for either test
**   material.
**   Although ther
F007 Main study
**
**   Microcrystalline waxes (HSW and HMPW)
**
**   Growth rates, food intakes and clinical condition
**   of animals fed either HSW or HMPW were unaffected by
```

** exposure
** No effects were observed at necropsy for either test
** material.
** Although there were minor organ weight changes, the authors
** did not consider them to be treatment-related unless a
** dose-related trend was apparent. The % increases (+%) or
** decreases (-%) at the various dietary concentrations are
** summarized below:

	Dietary concentration (%)			
Treatment	0.002	0.02	0.2	2.0
HMPW				
Abs. Male kidney		+5%		
Rel. Male kidney		+4%		
Abs. Male liver			+4	
Rel. Male liver			+3	
Abs. Female spleen			-5	
Rel. female spleen	-5			
HSW				
Abs. Female kidney		-3		
Rel. Male liver			+4	+3
Rel. Female liver	-5			

** The only minor hematological difference recorded was a 2%
** increase in hemoglobin concentration in males in the highest
** dose groups of both HSW and HMPW. Females were unaffected.
**
** Serum glucose levels were raised in all dose groups of
** animals fed HMPW and in all but the highest dose group of
** animals fed HSW.
** The % increases were:
**

Dietary concentration (%)	HMPW	HSW
0.002	13	9
0.02		8
0.2	10	11
2.0	8	

** No treatment-related histological changes were observed in
** either the HSW or the HMPW group animals.
**
**
** Main, reversal and tissue level studies
** Paraffin wax (LMPW)
**
** Although growth rates, food intakes and clinical condition
** of animals fed LMPW were unaffected by exposure, there was a
** spectrum of changes that occurred as follows.
** Organ weight changes were recorded in both sexes. Liver and
** spleen weights (absolute & relative) were increased at the 2
** and 0.2% dose levels. Although some reduction was observed
** after the reversal period in the 2% dose groups, they were
** still higher than the corresponding controls.

** Mesenteric lymph node weights were only available for the
** high dose level animals and these were increased following
** exposure to LMPW. Although the lymph node weights had
** reduced in the reversibility group they had not returned to
** normal by the end of the reversibility period.
** The % increase (+) or decrease (-) in the hematological
** parameters are shown in the following table. The statistical
** significance of the differences are also indicated
** (* p<= 0.05, ** p<= 0.01, *** p<= 0.001).
**

** Parameter	Dietary concentration (%)					
**	0.002	0.02	0.2	2.0		
** Males						
** RBC			+2*			
** Hemoglobin				+2*	-2*	-2**
** MCH				-2***	-2***	
** WBC		+16*	+20*	-3	+9	
** Neutrophils					+22**	+23**
** Platelets			-3	-3	-7**	-13***
**						
** Females						
** RBC					-4***	
** Reticulocytes						+43***
** Hemoglobin content						-6***
** Hematocrit						-4***
** MCH					-2***	
** WBC				+26***	+48***	
** Neutrophils					+45***	+89***
** Lymphocytes				+21*	+18*	+29***
** Monocytes					+35**	+103***
** Eosinophils						+41*
** Basophils Actual value					0.003***	0.004***
** (Control value = 0)						
** Platelets					-14***	-16***

**
** There were raised serum liver enzyme levels in the highest
** two dose groups of females but only at the highest dose in
** males. The enzymes affected were ALA, ALAT, ASAT and
** Gamma-GT. Serum bilirubin was also elevated in the highest
** dose group of females. Albumin/globulin ratios were reduced
** in the females at the highest 2 dose levels and in the
** highest dose level only for the males.
**
** Histopathological lesions were observed in many tissues and
** were of a severity and nature consistent with the age of the
** animals and were not considered to be treatment-related.
** However lesions in the liver, mesenteric lymph node, Ileum &
** jejunum and heart were considered to be compound-related.
** These were as follows:
**
** Liver
** Granulomas were observed in the livers of male and female
** rats at the highest 2 dose levels. At the highest dose
** centrilobular vacuolation was also observed. After the one
** month reversal period, granulomas were still present at the
** same incidence but their severity was less.
**

```
**   Mesenteric lymph node
**   The lymph node lesions comprised focal collections of
**   slightly vacuolated macrophages in the cortical region and
**   after one month's reversal these were reduced in severity.
**   Such lesions occurred  to varying degrees of severity at all
**   dose levels.
**
**   Ileum & jejunum
**   There was an increased incidence in macrophage accumulation
**   in Peyer's Patches in both sexes at the highest two dose
**   levels. There was also an increase in macrophage
**   infiltration of the lamina propria in the high dose females.
**
**   Heart
**   A focal inflammatory lesion was observed within the cusps of
**   the mitral valve. The lesion was characterised by an
**   increased cellularity of the valve with destruction of the
**   fibrous core. The lesion was observed in 11/20 males and
**   11/20 females at the highest dose level and 5/20 females at
**   the 0.2% group. Following the 28 day reversal period there
**   was still an increased incidence of the lesion but this was
**   less than that at the end of the 90-day feeding study.
**
**   Analysis of tissues for mineral hydrocarbons.
**   In the tissue level studies, no mineral hydrocarbons were found in the
*    kidneys of rats fed LMPW. However it was found in the perirenal fat,
*    liver and lymph nodes.
**   After the 28-day  reversal period, mineral hydrocarbon was still found in
*    these tissues, albeit at lower concentrations.
**   No mineral hydrocarbons were found in any of the tissues of animals fed
*    microcrystalline wax.
F008 IUC31
F020 2000
EOR
F002 28
F010 5.4
F004 1
F005 TS
F006 This study was carried out on six mineral oils and three
**   petroleum waxes (a paraffin wax and two microcrystalline
**   waxes). Only information on the waxes is included in this
**   robust summary. For additional details on the oils, see the Lubricat
F007 This study was carried out on six mineral oils and three
**   petroleum waxes (a paraffin wax and two microcrystalline
**   waxes). Only information on the waxes is included in this
**   robust summary. For additional details on the oils, see the Lubricating
*    Oil Basestocks Test plan.
**
**   The waxes were:
**
**   Paraffin wax
**    LMPW  A hydrotreated low melting point paraffin wax
**
**   Microcrystalline waxes
**    HSW   A clay-treated microcrystalline wax (High             Sulfur Wax)
**
**    HMPW  Hydrotreated microcrystalline wax, high         melting
```

point (High Melting Point Wax)

The characteristics of the three waxes are as follows (CONCAWE, 1993)

Property	Unit	Method (ASTM)	LMPW	HSW	HMPW
Color		D1550	L0.5	L0.5	L0.5
Penetration at 25°C	0.1 mm	D1321	18	27	13
Penetration at 40°C	0.1 mm	D1321	83	101	29
Congealing point	° C	D938	53.5	74.5	85.0
Drop melting point	° C	D127	55.6	82.0	91.4
Oil content	%	D721	0.1	1.8	1.3
Distillation ranges					
	° C	D86			
5%			369	411	510
50%			414	551	564
95%			467	698	721
Viscosity at 100 °C	mm2/s	D445	3.3	13.7	15.4
Density at 100 ° C	kg/m3	D1298	751.5	794.4	789.2
Ash content	%	D482	<0.01	0.01	<0.01
Refractive index at 100 °C		D1747	1.4230	1.4404	1.4393
Sulfur	ppm	D2622	5	2100	77
Acidity/alkalinity		USP XXIII	---------Pass--------		
UV absorbance		FDA 172.806	-------Pass--------		
Arsenic	ppm	AAS	<1	<1	<1
Chromium	ppm	AAS	<1	<1	<1
Cadmium	ppm	AAS	<1	<1	<1
Lead	ppm	AAS	<1	<1	<1
Carbon no. distribution		EWF/GC	19-42	20-74	22-80
Non-normal paraffin content	%	EWF/GC	11	52	28

```
**   The waxes were powdered and incorporated in the diet at
**   a concentration of 10% wt. This concentrate was further
**   diluted with control diet to achieve test diets containing
**   2.0, 0.2, 0.02 and 0.002% wax. Analytical studies were
**   carried out to ensure stability of wax in the diet and
**   homogeneity of mixing. Throughout the study diets were
**   analysed for mineral hydrocarbon content.
**
**   An extra control diet containing 2.0% coconut oil was also
**   prepared and this was also analysed throughout the study.
**
**   Results of anlytical measurements throughout the study
**   demonstrated that dietary mixing had been adequate and that
**   dietary levels were within acceptable limits.
F008 IUC31
F020 2001
EOR
F002 28
F010 5.4
F004 2
F005 RE
F006 BIBRA (1993)
**   A 90-day feeding study in the rat with two mineral waxes
**   identified as paraffin wax 64 (OFH-064) and micro/parrafin
**   wax mixture.
**   BIBRA Project No. 3.1205
F007 BIBRA (1993)
**   A 90-day feeding study in the rat with two mineral waxes
**   identified as paraffin wax 64 (OFH-064) and micro/parrafin
**   wax mixture.
**   BIBRA Project No. 3.1205
F008 IUC31
F020 2002
EOR
F002 28
F010 5.4
F004 2
F005 RE
F006 BIBRA (1999)
**   A subchronic 90-day dietary toxicity study of a low melting
**   point paraffin wax in two rat strains
**   Study No. 95-2394, API study No. HES1516-L-00880-Oral
F007 BIBRA (1999)
**   A subchronic 90-day dietary toxicity study of a low melting
**   point paraffin wax in two rat strains
**   Study No. 95-2394, API study No. HES1516-L-00880-Oral
F008 IUC31
F020 2003
EOR
F002 28
F010 5.4
F004 2
F005 RM
F006 The purpose of this study was to assess the safety in use of
**   a variety of oils and waxes for food contact applications.
**   As a follow up to this study, additional studies were
**   carried out on other finished wax samples and the results
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** are summ
F007 The purpose of this study was to assess the safety in use of
** a variety of oils and waxes for food contact applications.
** As a follow up to this study, additional studies were
** carried out on other finished wax samples and the results
** are summarized in the table below.
**
** The severity and incidence of the responses were related to
** the average molecular weights of the materials tested; the
** lower molecular weight materials causing the most severe
** effects (CONCAWE 1993).
**
** Sample Viscosity Carbon Average NOAEL
** @ 100°C Chain Mol. (mg/kg/day)
** (cSt) Length Weight
**
** LMPW 3.3 19-42 375 <2
** Blend 8 19-80 470 <2
** IMPW 6.3 21-49 480 <2
** HSW 13.7 20-74 600 2000
** HMPW 15.4 22-80 630 2000
**
** LMPW: Low melting point finished wax
** Blend: Blend of LMPW & HMPW
** IMPW: Intermediate melting point finished wax
** HSW: High sulfur wax
** HMPW: High melting point finished wax
**
** The findings from all the above studies allowed the EU
** Scientific Committee for Food (SCF 1995) to set ADIs for the
** high sulphur (HSW) and high molecular weight waxes (HMPW),
** but not for the lower molecular weight materials since for
** these NOELS had not been established.
**
** A further study has also been carried out in which Low
** Melting Point Wax was fed to F-344 and Sprague Dawley rats
** at dietary concentrations of 0.2 and 2.0% in the diet for 90
** days.
**
** The findings in the F-344 rats were essentially similar to
** those found in the studies summarized above but the Sprague
** Dawley rat was found to be a less sensitive strain.
**
** The only effects of treatment seen were an increase in
** mesenteric lymph node weight and microscopic findings in
** the same tissue (microgranulomas and reticuloendothelial
** cell hyperplasia). These effects were less severe and less
** frequent than those seen in the F-344 rats.
F008 IUC31
F020 2004
EOR
F002 28
F010 5.5
F004 1
F005 RM
F006 No data available
F007 No data available

F008 IUC31
F020 2005
EOR
F002 28
F010 5.6
F004 1
F005 RM
F006 No data available
F007 No data available
F008 IUC31
F020 2006
EOR
F002 28
F010 5.7
F004 1
F005 ME
F006 50 mg melted slack wax was painted on the skin of 50
** individually housed male mice, twice weekly for 80 weeks.
** The animals were shaved bi-weekly with electric clippers and
** the test material applied to the shaven intrascapular
** region.
** Treatm
F007 50 mg melted slack wax was painted on the skin of 50
** individually housed male mice, twice weekly for 80 weeks.
** The animals were shaved bi-weekly with electric clippers and
** the test material applied to the shaven intrascapular
** region.
** Treatment was continued for 80 weeks.
** A concurrent negative untreated control and a positive
** control (benzo-a-pyrene) was included in the study.
** The study was repeated using 25 mg/application, twice
** weekly.
F008 IUC31
F020 2007
EOR
F002 28
F010 5.7
F004 1
F005 RE
F006 Kane, M. L., Ladov, E. W., Holdsworth, C. E. and Weaver, N.
** K. (1984)
** Toxicological characteristics of refinery streams used to
** manufacture lubricating oils.
** American Journal of Industrial Medicine Vol 5. 183-200
F007 Kane, M. L., Ladov, E. W., Holdsworth, C. E. and Weaver, N.
** K. (1984)
** Toxicological characteristics of refinery streams used to
** manufacture lubricating oils.
** American Journal of Industrial Medicine Vol 5. 183-200
F008 IUC31
F020 2008
EOR
F002 28
F010 5.7
F004 1
F005 RL
F006 The report sumarises data from many studies and does not

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**   contain suficient detail for a full evaluation.
F007 The report sumarises data from many studies and does not
**   contain suficient detail for a full evaluation.
F008 IUC31
F020 2009
EOR
F002 28
F010 5.7
F004 1
F005 RM
F006 This report is a summary of results from an extensive
**   programme of studies. Consequently all the experimental
**   details have not been presented. The authors state that such
**   details are available in the original laboratory reports.
F007 This report is a summary of results from an extensive
**   programme of studies. Consequently all the experimental
**   details have not been presented. The authors state that such
**   details are available in the original laboratory reports.
F008 IUC31
F020 2010
EOR
F002 28
F010 5.7
F004 1
F005 RS
F006 No skin tumours developed in any of the mice to which slack
**   wax had been applied in either of the studies. The responses
**   in the control groups is not reported.
F007 No skin tumours developed in any of the mice to which slack
**   wax had been applied in either of the studies. The responses
**   in the control groups is not reported.
F008 IUC31
F020 2011
EOR
F002 28
F010 5.7
F004 1
F005 TS
F006 Slack wax CAS No. 64742-61-6
**   The sample was tested twice in the study summarised by Kane
**   et al.
F007 Slack wax CAS No. 64742-61-6
**   The sample was tested twice in the study summarised by Kane
**   et al.
F008 IUC31
F020 2012
EOR
F002 28
F010 5.7
F004 2
F005 ME
F006 50 mg petrolatum was painted on the skin of 50 individually
**   housed male mice, twice weekly for 80 weeks.
**   The animals were shaved bi-weekly with electric clippers and
**   the test material applied to the shaven intrascapular
**   region.
**   Treatment wa
```

F007 50 mg petrolatum was painted on the skin of 50 individually
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** The animals were shaved bi-weekly with electric clippers and
** the test material applied to the shaven intrascapular
** region.
** Treatment was continued for 80 weeks.
** A concurrent negative untreated control and a positive
** control (benzo-a-pyrene) was included in the study.
** The study was repeated using 25 mg/application, twice
** weekly.
F008 IUC31
F020 2013
EOR
F002 28
F010 5.7
F004 2
F005 RE
F006 Kane, M. L., Ladov, E. W., Holdsworth, C. E. and Weaver, N.
** K. (1984)
** Toxicological characteristics of refinery streams used to
** manufacture lubricating oils.
** American Journal of Industrial Medicine Vol 5. 183-200
F007 Kane, M. L., Ladov, E. W., Holdsworth, C. E. and Weaver, N.
** K. (1984)
** Toxicological characteristics of refinery streams used to
** manufacture lubricating oils.
** American Journal of Industrial Medicine Vol 5. 183-200
F008 IUC31
F020 2014
EOR
F002 28
F010 5.7
F004 2
F005 RL
F006 The report sumarises data from many studies and does not
** contain suficient detail for a full evaluation.
F007 The report sumarises data from many studies and does not
** contain suficient detail for a full evaluation.
F008 IUC31
F020 2015
EOR
F002 28
F010 5.7
F004 2
F005 RM
F006 This report is a summary of results from an extensive
** programme of studies. Consequently all the experimental
** details have not been presented. The authors state that such
** details are available in the original laboratory reports.
F007 This report is a summary of results from an extensive
** programme of studies. Consequently all the experimental
** details have not been presented. The authors state that such
** details are available in the original laboratory reports.
F008 IUC31
F020 2016
EOR
F002 28

F010 5.7
F004 2
F005 RS
F006 No skin tumours developed in any of the mice to which
** petrolatum had been applied in either of the studies. The
** responses in the control groups is not reported.
F007 No skin tumours developed in any of the mice to which
** petrolatum had been applied in either of the studies. The
** responses in the control groups is not reported.
F008 IUC31
F020 2017
EOR
F002 28
F010 5.7
F004 2
F005 TS
F006 Petrolatum CAS No. 8009-03-8
F007 Petrolatum CAS No. 8009-03-8
F008 IUC31
F020 2018
EOR
F002 28
F010 5.7
F004 3
F005 ME
F006 A single dose of 100 mg of one of the three petrolatum
** blends or stripped lard was administered subcutaneously into
** the intrascapular region of 28 day old mice. 50 male and 50
** female mice were used for each group and these were housed
** indiv
F007 A single dose of 100 mg of one of the three petrolatum
** blends or stripped lard was administered subcutaneously into
** the intrascapular region of 28 day old mice. 50 male and 50
** female mice were used for each group and these were housed
** individualy for the following 18 month observation period.
** The mice were allowed food and water ad-libitum.
** Growth, physical appearance and behaviour were observed
** throughout the study and special attention was paid to the
** injection site.
** Representative mice sacrificed at 9 months and all mice that
** died or were sacrificed at the end of the 18 month
** observation period were examined at autopsy for evidence of
** pathological change. Weights of liver, spleen and kidneys
** were recorded. After fixation, histological examination was
** made of: liver, spleen, stomach, small and large intestine,
** pancreas, kidney, urinary bladder, adrenal, throid, testis
** or ovary, salivary gland, lymph node, heart, muscle, lung,
** skin, spinal cord, brain, thymus and bone marrow and any
** macrocopically observed growths.
F008 IUC31
F020 2019
EOR
F002 28
F010 5.7
F004 3
F005 RE
F006 Oser, B. L., Oser, M., Carson, S. & Sternberg, S. S. (1965)

** Toxicologic Studies of Petrolatum in Mice and Rats
** Toxicology and Applied Pharmacology Vol 7, 382-401
F007 Oser, B. L., Oser, M., Carson, S. & Sternberg, S. S. (1965)
** Toxicologic Studies of Petrolatum in Mice and Rats
** Toxicology and Applied Pharmacology Vol 7, 382-401
F008 IUC31
F020 2020
EOR
F002 28
F010 5.7
F004 3
F005 RL
F006 This study is well conducted and reported, but was carried
** out prior to the need for GLP. Although survival of mice was
** poor, nevertheless the study is considered valid.
F007 This study is well conducted and reported, but was carried
** out prior to the need for GLP. Although survival of mice was
** poor, nevertheless the study is considered valid.
F008 IUC31
F020 2021
EOR
F002 28
F010 5.7
F004 3
F005 RS
F006 Growth rates, food intakes and food utilisation was
** unaffected by s.c. administration of any of the petrolatum
** samples when compared to the control group. The males
** consumed slightly more food than the females, but there were
** no differences
F007 Growth rates, food intakes and food utilisation was
** unaffected by s.c. administration of any of the petrolatum
** samples when compared to the control group. The males
** consumed slightly more food than the females, but there were
** no differences between the various treatment groups.
** Mortality was similar in the control and petrolatum groups
** and overal survival ranged between 12 and 24% at the end of
** the study (78 weeks).
** Liver, kidney and spleen weights were not affected by
** exposure to any of the petrolatum blends.
** Gross observations at autopsy were spread equally amongs all
** groups and were not specifically related to exposure to
** petrolatum.
** At about 7-9 months, there had been a significant rise in
** mortality in all groups and histopathlogical examination
** confirmead widespread leukemic infiltration with secondary
** septicemic involvement in some animals in all groups.
** Gross findings at the end of the study were consistent with
** ageing animals. The responses were largely either of a
** chronic inflammatory or fibrotic nature. Many of the
** observations in the lymphatic system showed chronic changes
** associated with the clearance of the foreign material that
** had been injected subcutaneously.
** There was no specific realtionship between tumour incidence
** and the test material injected.
**
** In conclusion, no toxic or carcinogenic response resulted as

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**   a consequence of the s.c. injection of a 100 mg dose of
**   either of the 3 petrolatum blends.
F008 IUC31
F020 2022
EOR
F002 28
F010 5.7
F004 3
F005 TS
F006 Three blends of petrolatum were examined. They were as
**   follows:
**
**   Blend A, a snow-white grade meeting USP XVI specifications.
**   This sample was a blend in equal proportions of six
**   commercially available materials, each meeting the US
**   specifica
F007 Three blends of petrolatum were examined. They were as
**   follows:
**
**   Blend A, a snow-white grade meeting USP XVI specifications.
**   This sample was a blend in equal proportions of six
**   commercially available materials, each meeting the US
**   specification.
**
**   Blend B, a white petrolatum, somewhat darker than Blend A,
**   but nevertheless meeting the USP XVI specification.
**   This blend was also prepared as a mixture of six
**   commercially avilable materials in equal proportions.
**
**   Blend C, a yellow petrolatum meeting NF XI specification.
**   This blend was prepared as a mixture in equal proortions of
**   5 commercially available products.
**
**   The three blends were kept with minimum air space
**   refrigerated in metal containers for the duration of the
**   study.
**
**   Analytical characteristics of the blends were as follows:
**
**   Blend     UV          Lovibond     Specific    Melting
**         absorptivity    color         gravity     point
**         (290 micron)  (2 in. cell)  (60 deg.C)  (deg.C)
**
**     A       0.136        2Y           0.830       53.5
**     B       0.424       12Y 0.5R      0.835       52.2
**     C       1.48        35Y 10R       0.844       51.3
**
**   Stripped lard was used as negative control substance.
F008 IUC31
F020 2023
EOR
F002 28
F010 5.7
F004 4
F005 ME
F006 50 rats of each sex, individually housed were fed diets
**   containing 5% of one of three blends of petrolatum
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**   ad-libitum for two years. A group of 100 rats of each sex
**   served as controls and were fed normal diet ad-libitum that
**   had been supple
F007 50 rats of each sex, individually housed were fed diets
**   containing 5% of one of three blends of petrolatum
**   ad-libitum for two years. A group of 100 rats of each sex
**   served as controls and were fed normal diet ad-libitum that
**   had been supplemented with 1% vitamin mix and 0.2% Aurofac
**   10.
**
**   The animals were observed daily for appearance, behaviour
**   and survival.
**
**   Weekly measurements were made of body weight for the first
**   12 weeks of the study and biweekly thereafter. Weekly
**   measurements were also made of food intake for the first 12
**   weeks for 10 rats of each sex fed the diets containing
**   petrolatum and for 20 rats of each sex fed control diet.
**
**   At 12, 26, 52, 72 & 100 weeks the following determinations
**   were made on repreentative animals from each of the groups:
**   red cell count and/or hematocrit, total and differential
**   white cell counts, hemoglobin content, blood glucose and
**   blood urea nitrogen levels.
**
**   Rats that died and survivors at the end of the study were
**   autopsied and the following organ weights were recorded:
**   liver, kidneys, spleen, heart, adrenals, thyroids and
**   pituitary.
**
**   For all rats that died, that were killed in a moribund state
**   or from representative surviving animals at the end of the 2
**   year feeding period (10 of each sex in the petrolatum
**   groups, 20 of each sex controls) the following organs were
**   fixed and examined histologicaly: liver, spleen, stomach,
**   large and small intestine, pancreas, kidney, urinary
**   bladder, adrenal, thyroid gland, testis or ovary, salivary
**   gland, lymph node, heart, lung, muscle, skin, spinal cord,
**   brain, thymus, bone marrow and "growths of any description".
F008 IUC31
F020 2024
EOR
F002 28
F010 5.7
F004 4
F005 RE
F006 Oser, B. L., Oser, M., Carson, S. & Sternberg, S. S. (1965)
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F008 IUC31
F020 2025
EOR
F002 28
F010 5.7
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F004 4
F005 RL
F006 This study is well conducted and reported, but was carried
**   out prior to the need for GLP. Nevertheless the study is
**   valid.
F007 This study is well conducted and reported, but was carried
**   out prior to the need for GLP. Nevertheless the study is
**   valid.
F008 IUC31
F020 2026
EOR
F002 28
F010 5.7
F004 4
F005 RS
F006 Growth rates were unaffected by exposure to petrolatum when
**   compared to controls.
**   Although there were small statistically significant
**   differences in food utilisation values between control and
**   some petrolatum exposed animals these were not
F007 Growth rates were unaffected by exposure to petrolatum when
**   compared to controls.
**   Although there were small statistically significant
**   differences in food utilisation values between control and
**   some petrolatum exposed animals these were not of biological
**   significance.
**   Survival at two years was unaffected when compared to
**   controls. Survival of males was approximately 68% and that
**   for females was 58%.
**   Neither hematological nor clinical chemical measurements
**   were affected by exposure to any of the petrolatum samples
**   either during or at the end of the study.
**   No differences were found at autopsy between petrolatum
**   exposed and control animals. Furthermore there were no
**   histological changes that could be attributed to dietary
**   exposure to petrolatum. Histological changes that occured
**   did so in both sexes and in all treatment and control groups
**   and were considered to be ageing related.
**   Neither of the 3 petrolatum blends caused an increased
**   tumour incidence in any tissue/organ examined.
F008 IUC31
F020 2027
EOR
F002 28
F010 5.7
F004 4
F005 TS
F006 Three blends of petrolatum were examined. They were as
**   follows:
**
**   Blend A, a snow-white grade meeting USP XVI specifications.
**   This sample was a blend in equal proportions of six
**   commercially available materials, each meeting the US
**   specifica
F007 Three blends of petrolatum were examined. They were as
**   follows:
**
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**   commercially available materials, each meeting the US
**   specification.
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**   Blend B, a white petrolatum, somewhat darker than Blend A,
**   but nevertheless meeting the USP XVI specification.
**   This blend was also prepared as a mixture of six
**   commercially available materials in equal proportions.
**
**   Blend C, a yellow petrolatum meeting NF XI specification.
**   This blend was prepared as a mixture in equal proortions of
**   5 commercially available products.
**
**   The three blends were kept with minimum air space
**   refrigerated in metal containers for the duration of the
**   study.
**
**   Analytical characteristics of the blends were as follows:
**
**   Blend     UV          Lovibond     Specific    Melting
**         absorptivity    color         gravity     point
**         (290 micron)  (2 in. cell)  (60 deg.C)  (deg.C)
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**     A       0.136         2Y           0.830       53.5
**     B       0.424       12Y 0.5R       0.835       52.2
**     C       1.48        35Y 10R        0.844       51.3
F008 IUC31
F020 2028
EOR
F002 28
F010 5.7
F004 5
F005 ME
F006 Three drops (approximately 60 microlitres) of a 15% solution
**   of amber petrolatum in isooctane was applied to the shaven
**   skin of the mice, twice weekly for their lifetimes.
**   30 male and 40 female mice were treated in this way.
**   A group of 50 m
F007 Three drops (approximately 60 microlitres) of a 15% solution
**   of amber petrolatum in isooctane was applied to the shaven
**   skin of the mice, twice weekly for their lifetimes.
**   30 male and 40 female mice were treated in this way.
**   A group of 50 males and 50 females served as vehicle
**   controls and received 60 microlitres of isooctane twice
**   weekly for the lifespan of each animal. Animals were housed
**   in groups of not more than 10 per cage.
**   The occurence of skin tumors and other lesions in the
**   treated area and other visible lesions was noted and their
**   progression recorded.
**   Histological confirmation of each lesion was confirmed after
**   autopsy of the respective animals.
F008 IUC31
F020 2029
EOR
F002 28
F010 5.7
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F004 5
F005 RE
F006 Lijinsky, W., Saffiotti, U. & Shubik, P. (1966)
** Skin Tumorigenesis by an Extract of Amber Petrolatum.
** Toxicology and Applied Pharmacology Vol. 8, 113-117
F007 Lijinsky, W., Saffiotti, U. & Shubik, P. (1966)
** Skin Tumorigenesis by an Extract of Amber Petrolatum.
** Toxicology and Applied Pharmacology Vol. 8, 113-117
F008 IUC31
F020 2030
EOR
F002 28
F010 5.7
F004 5
F005 RL
F006 The study was designed only to investigate skin
** carcinogenicity and consequently detailed pathological
** findings are not available. Detailed findings
** (histopathological) are not included in the paper, but the
** authors make reference to a sour
F007 The study was designed only to investigate skin
** carcinogenicity and consequently detailed pathological
** findings are not available. Detailed findings
** (histopathological) are not included in the paper, but the
** authors make reference to a source of such data.
F008 IUC31
F020 2031
EOR
F002 28
F010 5.7
F004 5
F005 RS
F006 Treatment with petrolatum caused moderate epidermal
** hyperplasia.
** The authors state that the incidence of internal tumors
** appeared within the limits observed in the control animals.
** Treatment did not appear to affect survival when compared t
F007 Treatment with petrolatum caused moderate epidermal
** hyperplasia.
** The authors state that the incidence of internal tumors
** appeared within the limits observed in the control animals.
** Treatment did not appear to affect survival when compared to
** controls as follows:
**
** Survival(%) at weeks
** Group 30 50 70
**
** Petrolatum
** Females 90 77 53
** Males 93 83 35
**
** Controls
** Females 90 80 64
** Males 90 54 32
**
** The skin tumor incidence is summarised below for the control
** and petrolatum groups. No data are included here for the

```
**   various extracts of petrolatum that were tested, even though
**   such data were given in the publication reviewed.
**
**   Group                  Total number of
**            Animals
**            with                                          Latency
**            tumors   Tumors   Carcinomas  Regressions   (weeks)
**
**   Petrolatum
**   Females    1        2*         -           1           100
**   Males      2        3**        -           2            69
**
**   Solvent
**   Females    -        -          -           -            -
**   Males      2        2          1           -            63
**
**     * one papilloma on eyelid
**    ** one papilloma under chin
F008 IUC31
F020 2032
EOR
F002 28
F010 5.7
F004 5
F005 TS
F006 15% solution of Amber Petrolatum (NF Grade) in isooctane.
F007 15% solution of Amber Petrolatum (NF Grade) in isooctane.
F008 IUC31
F020 2033
EOR
F002 28
F010 5.7
F004 6
F005 ME
F006 3 drops (approximately equivalent to 0.05 ml) of the
**   solution of wax or the solvent control was applied to the
**   skin of the intrascapular region over an area of approx. 2 X
**   2 cm. This treatment was continued 3 times weekly to groups
**   of mice
F007 3 drops (approximately equivalent to 0.05 ml) of the
**   solution of wax or the solvent control was applied to the
**   skin of the intrascapular region over an area of approx. 2 X
**   2 cm. This treatment was continued 3 times weekly to groups
**   of mice throughout the experiment. Observation was continued
**   until spontaneous death or until the animals were killed
**   when dying. All mice were subjected to a complete autopsy
**   followed by an histological examination of all abnormal
**   tissue.
**   Group sizes were approximately 60 male and 30 female for
**   each wax sample and 140 mice of each sex for controls.
F008 IUC31
F020 2034
EOR
F002 28
F010 5.7
F004 6
F005 RE
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F006 Shubik, P., Saffiotti, U., Lijinsky, W., Pietra, G.,
** Rappaport, H., Toth, B., Raha, C. R., Tomatis, L., Feldman,
** R. and Ramaha, H. (1962)
** Studies on the Toxicity of Petroleum Waxes.
** Toxicol. Appl. Pharmacol. Volume 4, Supplement 1-62
F007 Shubik, P., Saffiotti, U., Lijinsky, W., Pietra, G.,
** Rappaport, H., Toth, B., Raha, C. R., Tomatis, L., Feldman,
** R. and Ramaha, H. (1962)
** Studies on the Toxicity of Petroleum Waxes.
** Toxicol. Appl. Pharmacol. Volume 4, Supplement 1-62
F008 IUC31
F020 2035
EOR
F002 28
F010 5.7
F004 6
F005 RL
F006 Although not conducted to GLP, the study was nevertheless,
** robust and is acceptable for the purpose of assessing the
** skin carcinogenicity potential of paraffin wax solutions in
** benzene.
F007 Although not conducted to GLP, the study was nevertheless,
** robust and is acceptable for the purpose of assessing the
** skin carcinogenicity potential of paraffin wax solutions in
** benzene.
F008 IUC31
F020 2036
EOR
F002 28
F010 5.7
F004 6
F005 RS
F006 Survival rates of the mice were similar for treated and
** control animals with a better survival among females than
** males.
** Some desquamation and epilation occurred in the treated
** areas of skin after the first few applications and this
** persist
F007 Survival rates of the mice were similar for treated and
** control animals with a better survival among females than
** males.
** Some desquamation and epilation occurred in the treated
** areas of skin after the first few applications and this
** persisted throughout the study.
** Histologically, moderate epidermal hyperplasia was observed
** in both treated and control animals. The wax treated animals
** also had some focal areas of hyperplasia of the sebaceous
** glands. No degenerative or necrotic changes were observed.
**
** The skin tumor incidences are shown in the following table.
**

** Sample	No. of mice	Benign papillomas	Malignant carcinomas	Sebaceous gland adenomas	Other
** Wax 2	61 M	1			
**	30 F				

**

```
**   Wax 8   61 M       3            1
**           31 F       1
**
**   Wax 12  58 M       4                        1          1
**           34 F       1                        1
**
**   Wax 15  57 M       2
**           30 F       1
**
**   Wax 20  61 M       1                        2
**           36 F       1                        2
**
**   Benzene 59 M                    1
**           35 F       1
**
**   A number of other tumors were also observed at autopsy
**   (mainly lung adenomas, mammary carcinomas and malignant
**   lymphomas) but these were found in all groups and their
**   incidence was similar in wax treated groups and controls.
**   The authors judged that thse studies were negative.
F008 IUC31
F020 2037
EOR
F002 28
F010 5.7
F004 6
F005 TS
F006 5 waxes were selected from 36 samples on the basis of their
**   ultraviolet absorptivity, representing the range of aromatic
**   contents
**   Each of the 5 waxes was dissolved in warm benzene to achieve
**   15% solutions. These were warmed in a water bath
F007 5 waxes were selected from 36 samples on the basis of their
**   ultraviolet absorptivity, representing the range of aromatic
**   contents
**   Each of the 5 waxes was dissolved in warm benzene to achieve
**   15% solutions. These were warmed in a water bath prior to
**   application to the skin.
**   Additionally a benzene solvent control was included in the
**   study as well as  an aromatic extract (in is-octane) of one
**   of the waxes and a 15% solution in benzene of a
**   chromatographed wax.
F008 IUC31
F020 2038
EOR
F002 28
F010 5.7
F004 7
F005 ME
F006 Solutions of the waxes as well as the benzene alone were
**   applied three times weekly to the shorn skin of the
**   intrascapular region (approximately 10 X 10 cm) of 4 male
**   and 4 female rabbits. Each application consisted of
**   approximately 0.08 m
F007 Solutions of the waxes as well as the benzene alone were
**   applied three times weekly to the shorn skin of the
**   intrascapular region (approximately 10 X 10 cm) of 4 male
```

```
**   and 4 female rabbits. Each application consisted of
**   approximately 0.08 ml.
**   The authors state that a few rabbits were added in some
**   groups to compensate for death of other rabbits before one
**   year of treatment. Specific details are not provided.
F008 IUC31
F020 2039
EOR
F002 28
F010 5.7
F004 7
F005 RE
F006 Shubik, P., Saffiotti, U., Lijinsky, W., Pietra, G.,
**   Rappaport, H., Toth, B., Raha, C. R., Tomatis, L., Feldman,
**   R. and Ramaha, H. (1962)
**   Studies on the Toxicity of Petroleum Waxes.
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**   R. and Ramaha, H. (1962)
**   Studies on the Toxicity of Petroleum Waxes.
**   Toxicol. Appl. Pharmacol. Volume 4, Supplement 1-62
F008 IUC31
F020 2040
EOR
F002 28
F010 5.7
F004 7
F005 RL
F006 This study was not reported thoroughly, nor was it complete
**   at the time of publication. However it does provide
**   supportive information from a species other than the mouse.
F007 This study was not reported thoroughly, nor was it complete
**   at the time of publication. However it does provide
**   supportive information from a species other than the mouse.
F008 IUC31
F020 2041
EOR
F002 28
F010 5.7
F004 7
F005 RM
F006 This study had not been completed at the time of publication
**   of a paper on the toxicity of petroleum waxes (Shubik et
**   al).
**   However, the information is useful in assessing the skin
**   carcinogenicity of petroleum waxes since it provides data
**   fr
F007 This study had not been completed at the time of publication
**   of a paper on the toxicity of petroleum waxes (Shubik et
**   al).
**   However, the information is useful in assessing the skin
**   carcinogenicity of petroleum waxes since it provides data
**   from an additional species.
F008 IUC31
F020 2042
EOR
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F002 28
F010 5.7
F004 7
F005 RS
F006 Some reddening, desquamation and epilation of the painted
** skin area occured after a few paintings with the wax
** solutions and the benzene alone; these changes persisited
** throughout the study without any notable modifications.
** 2 small skin pa
F007 Some reddening, desquamation and epilation of the painted
** skin area occured after a few paintings with the wax
** solutions and the benzene alone; these changes persisited
** throughout the study without any notable modifications.
** 2 small skin papillomas were observed in the male group
** painted with one of the waxes. One of these papillomas
** developed after 48 weeks of treatment and was still present
** at the 105th week. The other papilloma developed after 93
** weeks and regressed at the 110th week.
** No other skin lesions were found in any of the groups.
F008 IUC31
F020 2043
EOR
F002 28
F010 5.7
F004 7
F005 TS
F006 5 waxes were selected from 36 samples on the basis of their
** ultraviolet absorptivity, representing the range of aromatic
** contents
** Each of the 5 waxes was dissolved in warm benzene to achieve
** 15% solutions. These were warmed in a water bath
F007 5 waxes were selected from 36 samples on the basis of their
** ultraviolet absorptivity, representing the range of aromatic
** contents
** Each of the 5 waxes was dissolved in warm benzene to achieve
** 15% solutions. These were warmed in a water bath prior to
** application to the skin.
** Additionally a benzene solvent control was included in the
** study.
F008 IUC31
F020 2044
EOR
F002 28
F010 5.7
F004 8
F005 ME
F006 Each of the five waxes were fed ad-libitum to male and
** female rats at a dietary concentration of 10% for 2 years.
** An additional group of 140 male and 157 females were fed
** control diet.
** The rats inspected and weighed every second week and a
F007 Each of the five waxes were fed ad-libitum to male and
** female rats at a dietary concentration of 10% for 2 years.
** An additional group of 140 male and 157 females were fed
** control diet.
** The rats inspected and weighed every second week and all
** gross lesions were recorded. This was continued until the

```
**   rats died or were killed when dying and were then submitted
**   to complete autopsy followed by histological examination of
**   all abnormal tissue.
F008 IUC31
F020 2045
EOR
F002 28
F010 5.7
F004 8
F005 RE
F006 Shubik, P., Saffiotti, U., Lijinsky, W., Pietra, G.,
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**   R. and Ramaha, H. (1962)
**   Studies on the Toxicity of Petroleum Waxes.
**   Toxicol. Appl. Pharmacol. Volume 4, Supplement 1-62
F008 IUC31
F020 2046
EOR
F002 28
F010 5.7
F004 8
F005 RL
F006 Study not carried out acording to GLP and only "abnormal"
**   tissue examined histologically.
**   Study provided supportive information only and coul not be
**   used as a definitive study.
F007 Study not carried out acording to GLP and only "abnormal"
**   tissue examined histologically.
**   Study provided supportive information only and coul not be
**   used as a definitive study.
F008 IUC31
F020 2047
EOR
F002 28
F010 5.7
F004 8
F005 RS
F006 Survival rates and growth rates were unaffected by oral
**   exposure to any of the waxes tested.
**   A number of tumors were found in all groups at autopsy. The
**   incidence of each tumor type was reported. The number of
**   tumour bearing animals was sim
F007 Survival rates and growth rates were unaffected by oral
**   exposure to any of the waxes tested.
**   A number of tumors were found in all groups at autopsy. The
**   incidence of each tumor type was reported. The number of
**   tumour bearing animals was similar to that of controls and
**   furthermore the incidence of the various tumor types was
**   also similar in treated and control animals.
**   No other toxic effects were found at histological
**   examination.
**   The authors concluded that the five waxes were devoid of
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**   carcinogenic or other toxic action when fed at a level of
**   10% in the diet.
F008 IUC31
F020 2048
EOR
F002 28
F010 5.7
F004 8
F005 TS
F006 5 waxes were selected from 36 samples on the basis of their
**   ultraviolet absorptivity, representing the range of aromatic
**   contents
**   Each of the 5 waxes was ground into a powder and added to
**   powdered diet and mixed in the proportion 1:9 w/w.
F007 5 waxes were selected from 36 samples on the basis of their
**   ultraviolet absorptivity, representing the range of aromatic
**   contents
**   Each of the 5 waxes was ground into a powder and added to
**   powdered diet and mixed in the proportion 1:9 w/w.
F008 IUC31
F020 2049
EOR
F002 28
F010 5.7
F004 9
F005 ME
F006 Approximately 15 mg of warmed test material were applied as
**   a thin film by means of a small brush on Monday, Wednesday
**   and Friday to the shorn scapular region of groups of 30
**   albino male mice. Test material application was continued
**   until d
F007 Approximately 15 mg of warmed test material were applied as
**   a thin film by means of a small brush on Monday, Wednesday
**   and Friday to the shorn scapular region of groups of 30
**   albino male mice. Test material application was continued
**   until death. After tumors had appeared the test materials
**   were applied around the viable base of the growths, not on
**   their often "dead tops".
**
**   For each material at autopsy, sections were taken of
**   representative tumors and any internal lesions of interest.
**   These tissue sections were then examined microscopically.
**   For each test material a cancer and a tumor index was
**   calculated as follows:
**
**   Tumor index = 100 X
**
**   Total No of animals in which tumors developed/
**   Original No. animals less No dead at 90 days without tumors
**
**   Cancer Index = 100 X
**   Total No animals in which cancer developed/
**   Original No less No. dead at 90 days from causes oter than
**   cancer
**
**   Potency was calculated:
**    Cancer index / Tumor index
```

F008 IUC31
F020 2050
EOR
F002 28
F010 5.7
F004 9
F005 RE
F006 Dietz, W. A., King Jr., W. H., Priestley Jr. W. and Rehner,
** J. (1952)
** Properties of high boiling petroleum products
** Ind. Eng. Chem. Vol. 44., No 8., pp. 1818-1827
F007 Dietz, W. A., King Jr., W. H., Priestley Jr. W. and Rehner,
** J. (1952)
** Properties of high boiling petroleum products
** Ind. Eng. Chem. Vol. 44., No 8., pp. 1818-1827
F008 IUC31
F020 2051
EOR
F002 28
F010 5.7
F004 9
F005 RE
F006 Smith, W. E., Sunderland, D. A. and Sugiura, K. (1951)
** Experimental analysis of the carcinogenic activity of
** certain petroleum products.
** Arch. Ind. Hyg. Occ. Med. Volume 4, pp 299-314
F007 Smith, W. E., Sunderland, D. A. and Sugiura, K. (1951)
** Experimental analysis of the carcinogenic activity of
** certain petroleum products.
** Arch. Ind. Hyg. Occ. Med. Volume 4, pp 299-314
F008 IUC31
F020 2052
EOR
F002 28
F010 5.7
F004 9
F005 RL
F006 The study summarized here was conducted to identify the
** carcinogenic component(s) of slack waxes.
** Although not conducted to GLP and lacking experimental
** deatils the study is important since it identifies the
** residual oil in the slack wax an
F007 The study summarized here was conducted to identify the
** carcinogenic component(s) of slack waxes.
** Although not conducted to GLP and lacking experimental
** deatils the study is important since it identifies the
** residual oil in the slack wax and not the paraffins as being
** responsible for carcinogenic activity.
F008 IUC31
F020 2053
EOR
F002 28
F010 5.7
F004 9
F005 RS
F006 Results are summarized in the following two tables:
**

** Slack waxes
**
** Wax   Oil   CI/TI at Days
** Sample (%)*   250   450
**
** 145   25   4/23 8/10***
** 147   17   0/3   7/7
** 150   20   0/0   4/4
** 141   10   0/3   0/7
** 142   21   0/4   0/4
** 144   21   0/4   0/4
** 140   20
F007 Results are summarized in the following two tables:
**
** Slack waxes
**
** Wax   Oil   CI/TI at Days
** Sample (%)*   250   450
**
** 145   25   4/23 8/10***
** 147   17   0/3   7/7
** 150   20   0/0   4/4
** 141   10   0/3   0/7
** 142   21   0/4   0/4
** 144   21   0/4   0/4
** 140   20   4/7   4/4***
** 146   12   0/0   4/4
**
**
** Aromatic extracts
** Sample Aromatic   CI/TI at Days
**   (%)**   250   450
** 231   18   14/38 24/38****
** 233   0   19/30 23/35****
** 235   12   17/35 17/43****
** 228   7   3/17 14/34
** 229   0   0/0   0/13
** 230   12   0/42 8/30***/*****
** 231   11   4/22 4/30
** 232   8   0/8   4/10
**
**   *   Oil content of the slack waxes (w/w)
**   **   Aromatics content of the slack wax (w/w)
**   ***   The lower tumor index (TI) at the later date   is due
** to the spontaneous disappearance of   some papillomas
**   **** The experiment was discontinued after 335   days
**   ***** The experiment was discontinued after 490   days
**
** The authors concluded that the slack waxes showed only a low
** order of carcinogenicity at 250 days. However by 450 days
** every sample of salck wax had elicited papillomas and for 5
** of them cancers as well.
** The aromatic extracts on the other hand exhibited a greater
** potency. At 250 days all but one sample had produced
** papillomas and 5 samples had produced cancers. At 450 days
** all but one sample had elicited cancers and all had elicited
** papillomas.

```
**
**
**   The authors concluded that the carcinogenicity of slack wax
**   1.     Can be attributed to the aromatic compounds found in  the
**   oils from which the waxes were pressed and which       are
**   retained on the waxes as impurities.
**   2.     Is not due to paraffins.
**
**   Another study from the same laboratory (Dietz et al, 1952)
**   on 11 slack waxes (it is unclear whether some were the same
**   samples as in Smith et al, 1951) produced similar results.
**   The tumor potency of each sample was low to marginal.
F008 IUC31
F020 2054
EOR
F002 28
F010 5.7
F004 9
F005 TS
F006 Eight slack waxes and eight aromatic hydrocarbon extracts
**   derived from the slack waxes were tested.
**   [Because of the lack of detail in the publication it is not
**   possible to establish whic aromatic extract from which
**   specific slack wax].
**
**    Th
F007 Eight slack waxes and eight aromatic hydrocarbon extracts
**   derived from the slack waxes were tested.
**   [Because of the lack of detail in the publication it is not
**   possible to establish whic aromatic extract from which
**   specific slack wax].
**
**    The extracts were obtained by eluting, with an unspecified
**   solvent, silica gel columns charged with the individual
**   slack waxes.  No additional information was provided on the
**   preparation of the aromatic test materials.
**   [However, in parallel studies on aromatic extracts collected
**   from catalytically cracked oils, the investigators reported
**   that the silica gel columns were eluted first with n-heptane
**   to collect non-aromatic components of the oils and then with
**   acetone to recover the aromatic components. In the parallel
**   studies the recovered aromatics were tested on mice after
**   evaporation of the acetone.]
F008 IUC31
F020 2055
EOR
F002 28
F010 5.7
F004 10
F005 ME
F006 A single wax disc (2 cm. diameter, 2 mm. thick and weighing
**   0.5 g) was implanted subcutaneously in groups of
**   approximately 45 male and 50 female Swiss mice. This was
**   done for 5 different waxes.
**   Additionally, 0.5 g of one of the waxes was im
F007 A single wax disc (2 cm. diameter, 2 mm. thick and weighing
**   0.5 g) was implanted subcutaneously in groups of
```

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**   approximately 45 male and 50 female Swiss mice. This was
**   done for 5 different waxes.
**   Additionally, 0.5 g of one of the waxes was implanted as a
**   powder in a further group of 48 and 46 female Swiss mice.
**   The animals and their controls were observed for their
**   lifetimes.
F008 IUC31
F020 2056
EOR
F002 28
F010 5.7
F004 10
F005 RE
F006 Shubik, P., Saffiotti, U., Lijinsky, W., Pietra, G.,
**   Rappaport, H., Toth, B., Raha, C. R., Tomatis, L., Feldman,
**   R. and Ramaha, H. (1962)
**   Studies on the Toxicity of Petroleum Waxes.
**   Toxicol. Appl. Pharmacol. Volume 4, Supplement 1-62
F007 Shubik, P., Saffiotti, U., Lijinsky, W., Pietra, G.,
**   Rappaport, H., Toth, B., Raha, C. R., Tomatis, L., Feldman,
**   R. and Ramaha, H. (1962)
**   Studies on the Toxicity of Petroleum Waxes.
**   Toxicol. Appl. Pharmacol. Volume 4, Supplement 1-62
F008 IUC31
F020 2057
EOR
F002 28
F010 5.7
F004 10
F005 RL
F006 Although the study was not GLP compliant it nevertheless was
**   properly conducted and reported.
F007 Although the study was not GLP compliant it nevertheless was
**   properly conducted and reported.
F008 IUC31
F020 2058
EOR
F002 28
F010 5.7
F004 10
F005 RS
F006 Tumors developed at the implantation sites of the wax discs.
**   No tumors developed at the site s of the powdered wax.
**
**   This finding is consistent with other reorts on the
**   tumorigenicity of implanted inert materials. It is generally
**   beleived t
F007 Tumors developed at the implantation sites of the wax discs.
**   No tumors developed at the site s of the powdered wax.
**
**   This finding is consistent with other reorts on the
**   tumorigenicity of implanted inert materials. It is generally
**   beleived that tumorigenicity at subcutaneous implantation
**   sites is a function of the physical form of the material
**   rather than of the material itself. If however, the material
**   had been tumorigenic it would be expected that tumors would
**   have developed at the site of the implanted powder.
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F008 IUC31
F020 2059
EOR
F002 28
F010 5.7
F004 12
F005 RE
F006 Schmahl, D. and Reiter A. (1953)
** Experiments to create cancer with liquid paraffin, yellow
** petrolatum and wool fat.
** Arxneimittel-Forschungen Vol 3, pp 403-406
F007 Schmahl, D. and Reiter A. (1953)
** Experiments to create cancer with liquid paraffin, yellow
** petrolatum and wool fat.
** Arxneimittel-Forschungen Vol 3, pp 403-406
F008 IUC31
F020 2060
EOR
F002 28
F010 5.7
F004 12
F005 RL
F006 This study is of historical interest only and is included
** for completeness only.
F007 This study is of historical interest only and is included
** for completeness only.
F008 IUC31
F020 2061
EOR
F002 28
F010 5.7
F004 12
F005 RM
F006 The following is taken from the method section of an English
** translation of the German report:
** "
** Liquid paraffin (DAB. 6) was injected into 30 rats, 2.5 ml
** once subcutaneously and intraperitoneally in a total dose
** of 9 ml per animal di
F007 The following is taken from the method section of an English
** translation of the German report:
** "
** Liquid paraffin (DAB. 6) was injected into 30 rats, 2.5 ml
** once subcutaneously and intraperitoneally in a total dose
** of 9 ml per animal divided over 15 individual injections
** over a period of 40 weeks. Another 30 rats obtained the
** liquid paraffin in the food. The total dose was 136
** ml/animal in 500 days.
**
** Yellow vaseline (DAB. 6) was also injected after warming.
** Eight rats obtained 3 ml intraperitoneally and 26 rats 1 ml
** subcutaneously besides. All animals were observed until
** spontaneous death......."
**
** The following is taken from the results section of the
** publication.
** "

```
**    In the experiment with vaseline a tumor developed at  the
**   injection point after a latent period of 658     days.
**   Histologically this tumor turned out to be an
**    osteo-sarcoma. ......"
F008 IUC31
F020 2062
EOB
C
X
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